

# **DSJ1&2-PR Exh 538**

# Marketing Plan 2007

**FENTORA<sup>TM</sup>**  
*fentanyl buccal tablet @*

# Presentation Overview

- Launch Plan Assessment
- Market Situation Analysis
  - Disease Overview
  - Opioid Market
  - Competitive Analysis
  - Environmental Trends
- Product Situation Analysis
  - Profile & Position
  - Actiq Performance
  - FENTORA Performance
- SWOT Analysis & Key Issues
- Marketing Strategy
  - Mission & Strategic Vision
  - Objectives, CSFs & Strategies
  - LCM / Clinical Plan
  - Targeting
- Tactical Plan
  - NSM Plan

Terrence Terifay

Matt Napoletano

Michael Richardson

John Messina

Paula Castagno  
Cynthia Condodina

# Where We Were

## Launch Plan Assessment & Situation Analysis

**FENTORA<sup>TM</sup>**  
*fentanyl buccal tablet* ®

# Executing the Plan

- In order to overcome any challenge, two things are vital for success to be achieved
  - Leadership
  - Execution

} Sales & Marketing Synergy
- 3 main attributes of leadership
  - Passion
  - Style
  - Perseverance
- “Luck doesn’t favor the lucky, it favors the prepared team” – Vince Lombardi
- “Success is where preparation and opportunity meet” – Bobby Unser

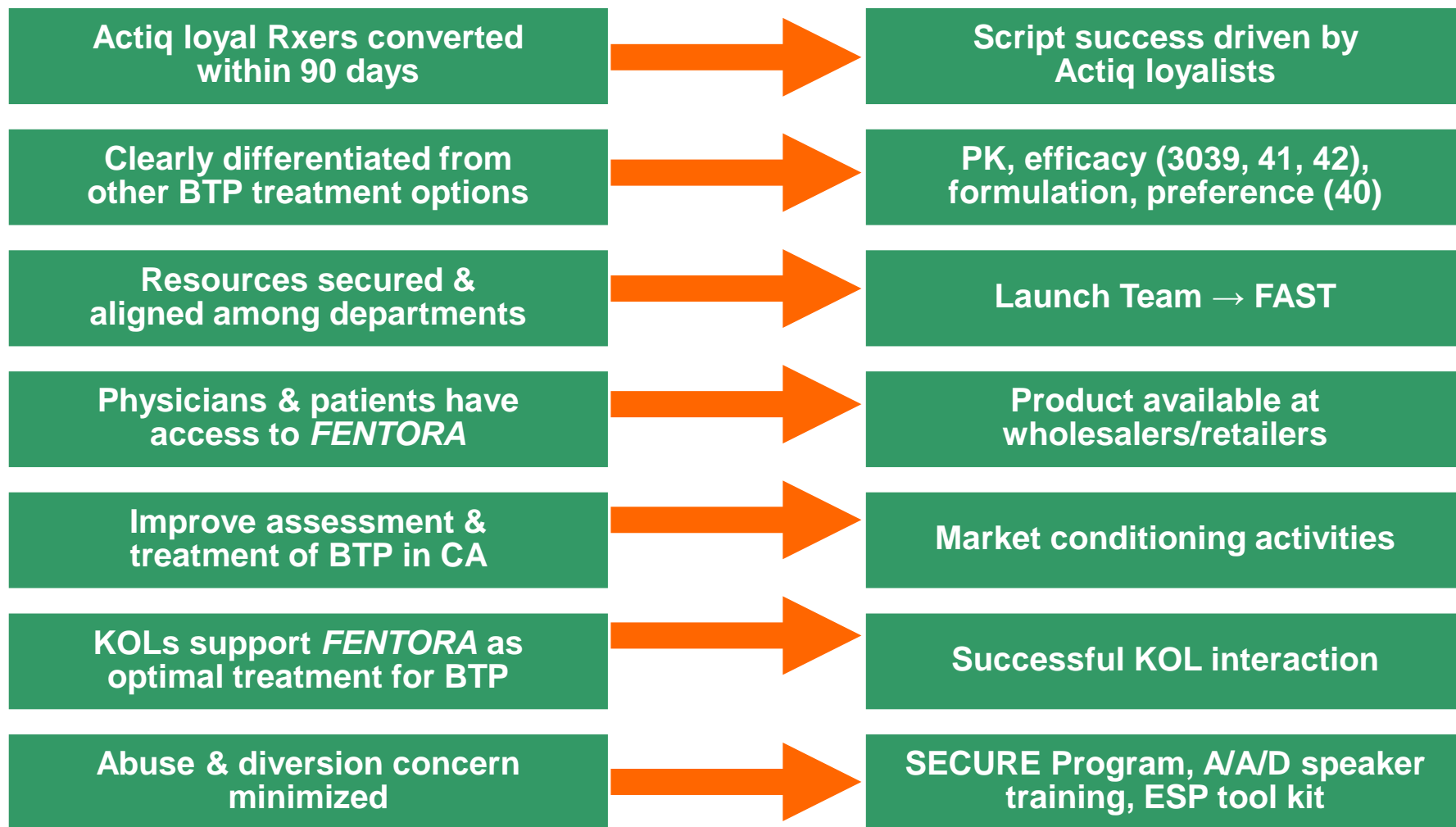
# Market Conditioning & Brand Awareness 2005 - 2006

Case: 1:17-md-02804-DAP Doc #: 2557-18 Filed: 08/30/19 6 of 150 PageID #: 411813

- PF & OV Tech campaigns launched
  - Journal Ads, 3-wave direct mail, animation, booth panels, etc.
- BTP campaign launched
  - Journal Ads, 3-wave direct mail, animation, DA booth, brochures, etc.
- Interviewed 500+ physicians, patients and pharmacists to develop branding, messaging and pricing
- 400+ Physicians provided consultation and advice on commercial and clinical plans
- Public relations and media outreach
- Publications and education presence at major congresses
- 285 Speakers Trained
- 150 field personnel trained, motivated and focused

**70% of core Actiq prescribers were ready for *FENTORA* & we were ready for them**

# FENTORA CSFs & Accomplishments



# Market Situation

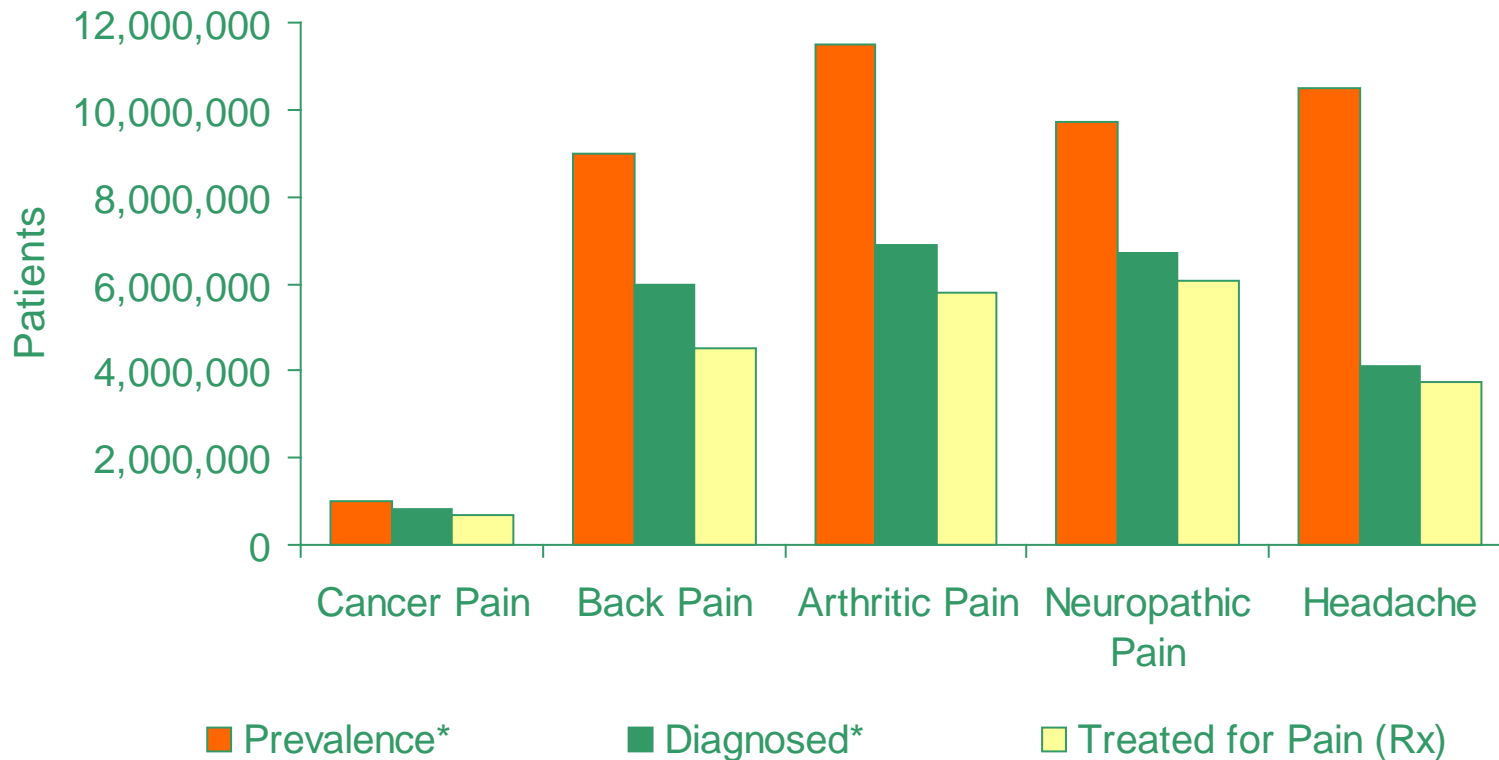
## Disease Overview

***FENTORA***<sup>TM</sup>  
*fentanyl buccal tablet* ®



# Chronic Pain: Prevalence

- Chronic pain prevalence, diagnosed & treated by underlying conditions



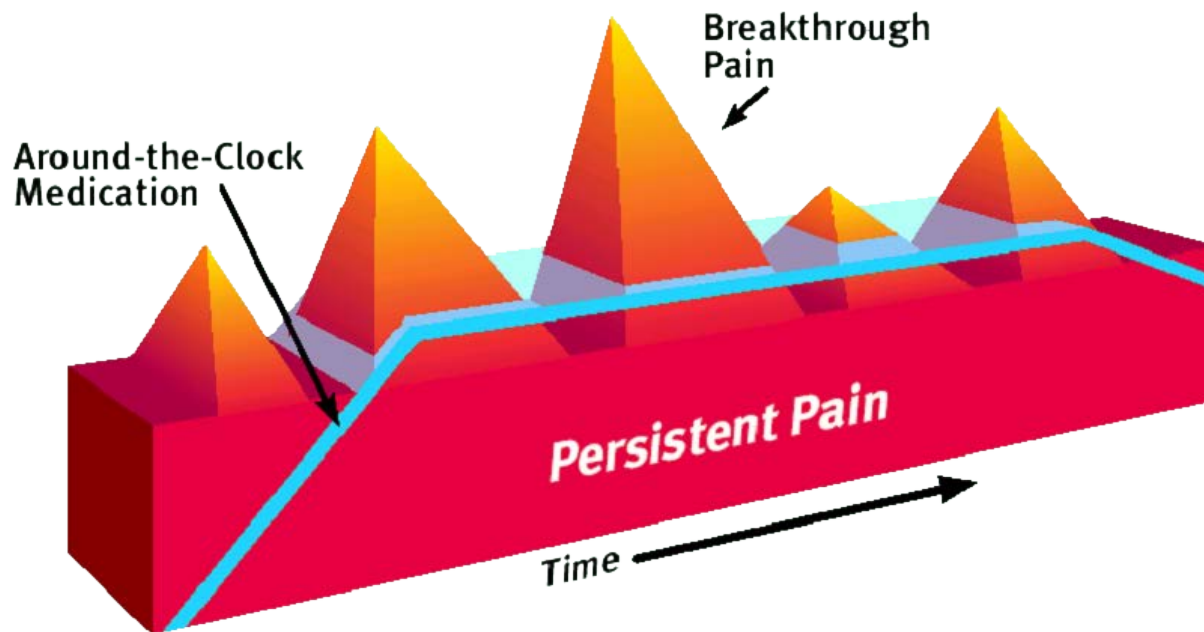
# Chronic Pain: Components

## Baseline or Persistent Pain

Pain that is continuous throughout the day ( $\geq 12$  hours/day) and is managed with around-the-clock medication.

## Breakthrough Pain

Transitory exacerbation, or flare, of moderate-to-severe pain that occurs in patients on chronic opioid therapy with otherwise stable persistent pain.



# BTP Prevalence & Characteristics

	Cancer BTP (N =63) <sup>1</sup>	Noncancer BTP (N=228) <sup>4</sup>
Prevalence	64% to 89% <sup>1,2</sup>	74%
Median Episodes/Day	4 to 7 <sup>1-3</sup>	2
Time to Peak Intensity	43% in 3 min	50% in 5 min
Median Duration	30 min	60 min
Incident Related	55%	92%
Pathophysiology	<ul style="list-style-type: none"> <li>• somatic (33%)</li> <li>• visceral (20%)</li> <li>• neuropathic (27%)</li> <li>• mixed (20%)</li> </ul>	<ul style="list-style-type: none"> <li>• somatic (38%)</li> <li>• visceral (4%)</li> <li>• neuropathic (18%)</li> <li>• mixed (40%)</li> </ul>

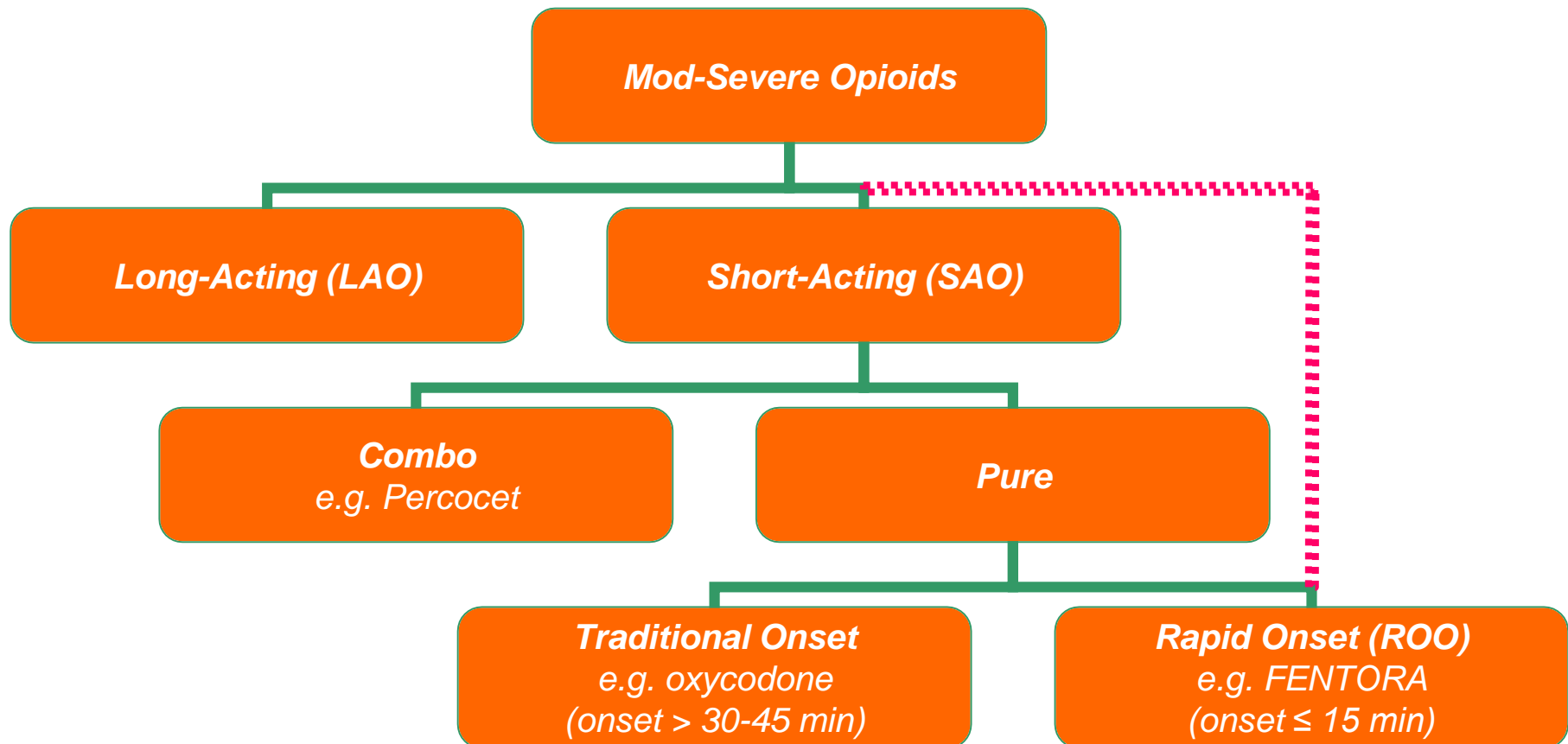
<sup>1</sup>Portenoy, Hagen. *Pain*. 1990;41:273-281

<sup>2</sup>Zeppetella. *J Pain Symptom Manage*. 2000;20:87-92

<sup>3</sup>Portenoy et al. *Pain*. 1999;81:129-134

<sup>4</sup>Portenoy, et al. APS. 2005

# BTP Pain: Current Treatment

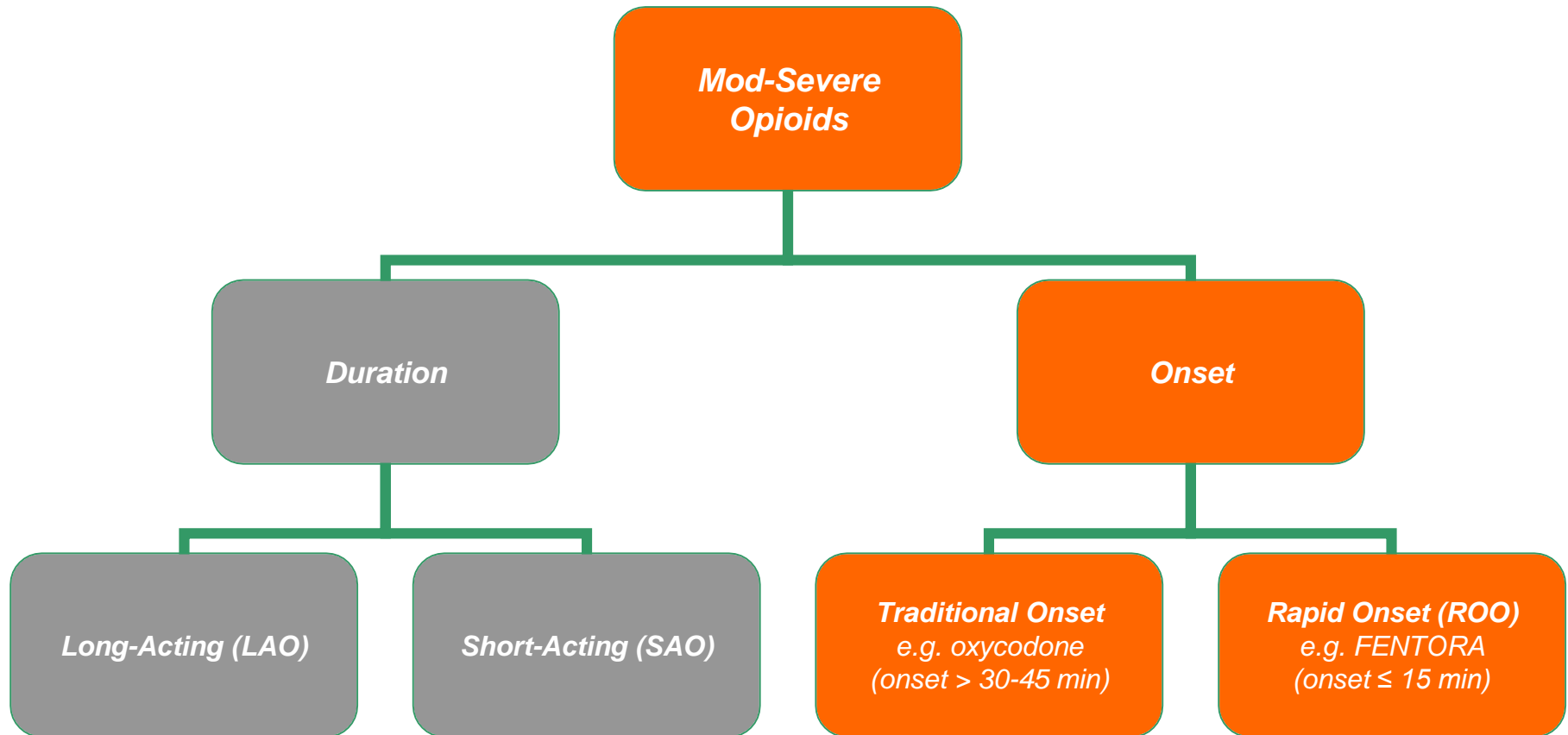


# BTP Treatment Patterns

Typical Course of Action	# of BTP Episodes	
	$\leq 3$	$\geq 4$
Increase dose of LAO	34%	64%
Increase frequency of LAO	7%	12%
Increase frequency of SAO	21%	10%
Switch the LAO	2%	7%
Increase dose of SAO	28%	4%
Switch the SAO	3%	2%

- The most common treatment choice is to increase the dose of LAOs regardless of # of episodes
- The next most common approach is to either increase the frequency or dose of the SAO
- Switching to an alternative SAO is typically the last course of action

# BTP Pain: Treatment Evolution



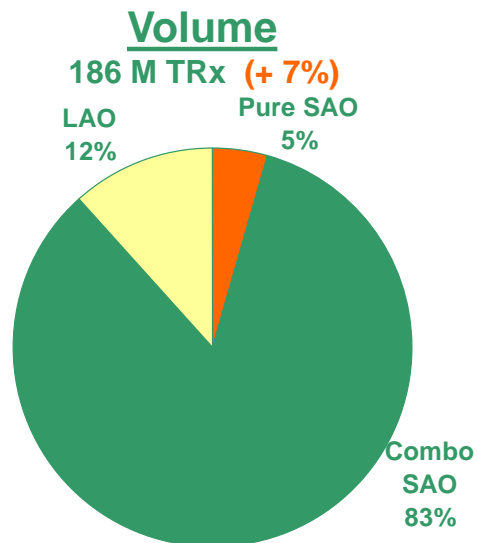
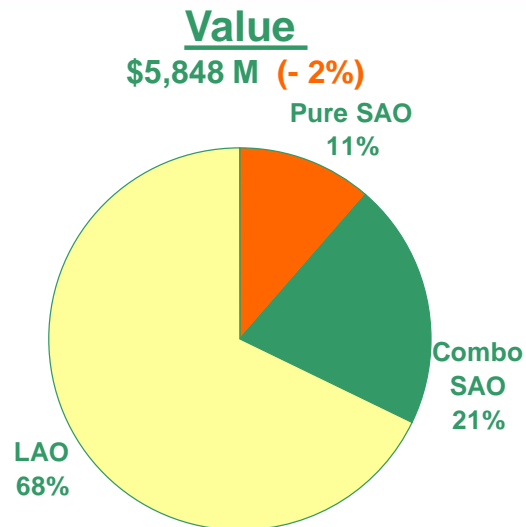
# Market Situation

## Opioid Market

**FENTORA<sup>TM</sup>**  
*fentanyl buccal tablet* ®

# Market Overview

## Opioid Market 2005



### Size & Growth

- Opioid market is large
- Value is relatively flat over '04 due to generic LAO entry
- Volume up 7%

### Share

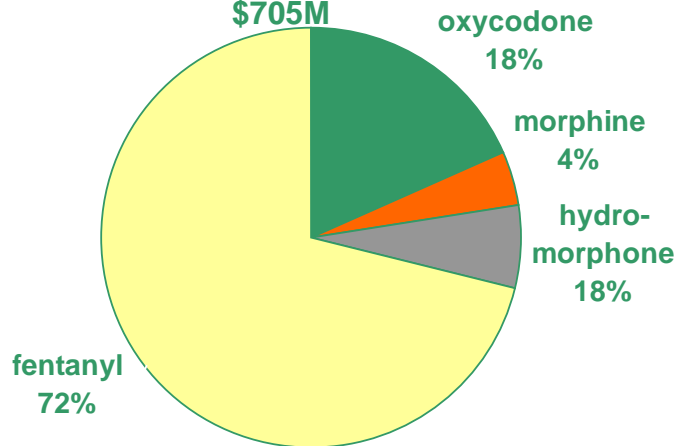
- LAOs make up the largest share in terms of value
- SAOs make up the largest share in terms of volume



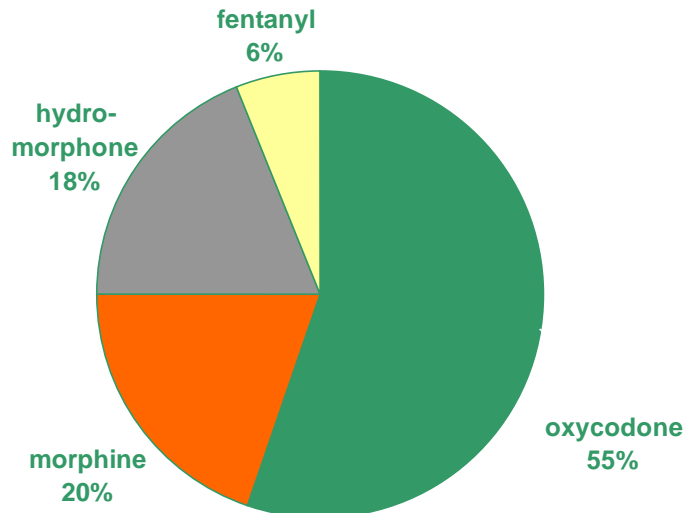
# Pure SAO

## 2005

### Value \$705M



### Volume \$7.8M TRxs



### Size & Growth

- Pure SAO market is moderate
- Value & Volume have strong growth (>20%)

### Share

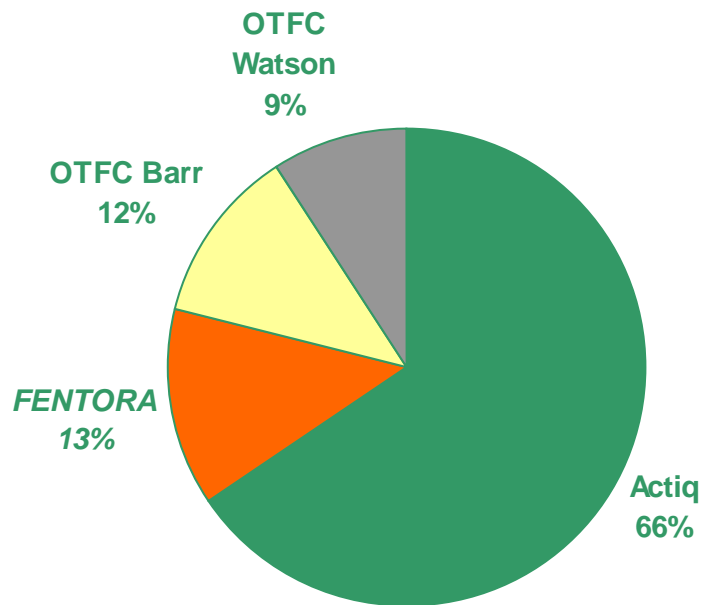
- Actiq (fentanyl) made up largest share in terms of value
  - Only branded Pure SAO in 2005
- Oxycodone dominates in terms of volume
  - Fentanyl is often perceived as more potent analgesic & held in reserve

Source: IMS, NPA Audit. Moving annual total, 2Q2005.

# ROO Market

## October 2006

Volume (TRx)



### Prior to Oct 2006

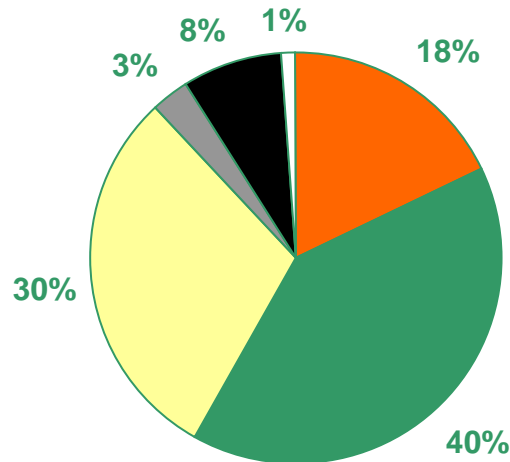
- Actiq was sole ROO
- Consistent Value growth (more recently due to price increases)
- Strong Volume growth up to 2004 (reached plateau)

### As of Oct 2006

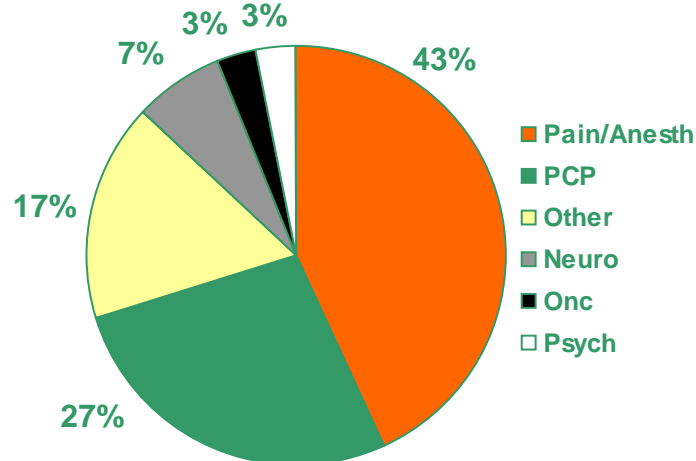
- Generic OTFC introduced
  - Captured 21% of volume
- *FENTORA* introduced
  - Captured 13% of volume

# Customer Analysis\*

## Pure SAO by Specialty (TRx)



## Actiq by Specialty (TRx)



## Pure SAO Sub-Class

- PCPs generate largest volume
- Pain/Anesth only account for 18% of volume

## ROO Sub-Class (Actiq)

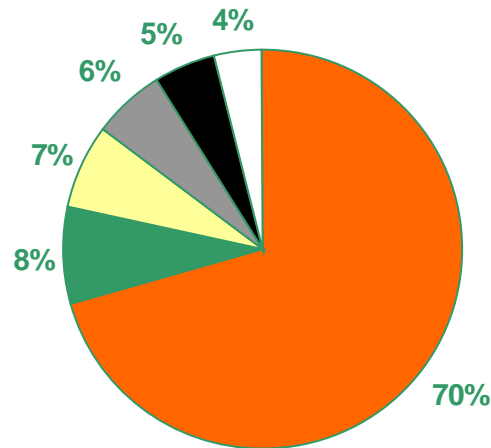
- Pain/Anesth generate largest volume
  - Typically early adopters of emerging therapies
- The other major contributors are PCPs & Other

\*Pain Medicine, Anesthesiology & Physical Medicine and Rehab

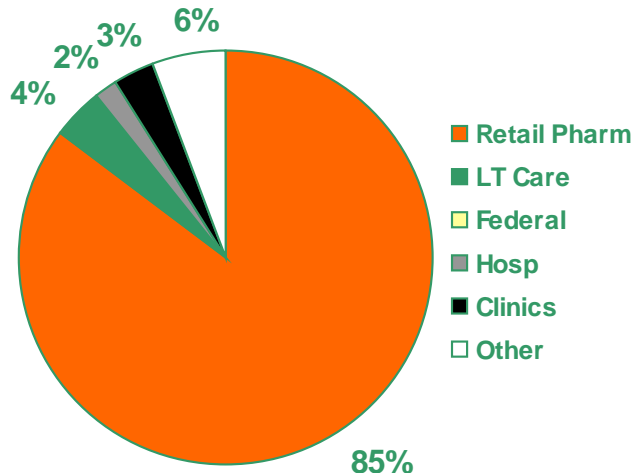
\*\*Source: IMS Prescribers - NPA TRx – Class of Trade – NSP Units

# Trade Class

## Pure SAO Distribution Channels



## ROO (Actiq) Distribution Channels



- Vast majority of product moves through Retail Pharmacy
- Modest penetration of Pure SAO in non-retail segment
  - Non-Retail often provides spill-over effect
- Less penetration by ROO (Actiq) sub-class in non-retail segment
  - Non-retail segment is price sensitive

\*Pain Medicine, Anesthesiology & Physical Medicine and Rehab

\*\*Source: IMS Prescribers - NPA TRx – Class of Trade – NSP Units

# Market Situation

## Competitive Analysis

***FENTORA***<sup>TM</sup>  
*fentanyl buccal tablet* ®

# Major Chronic Pain Players

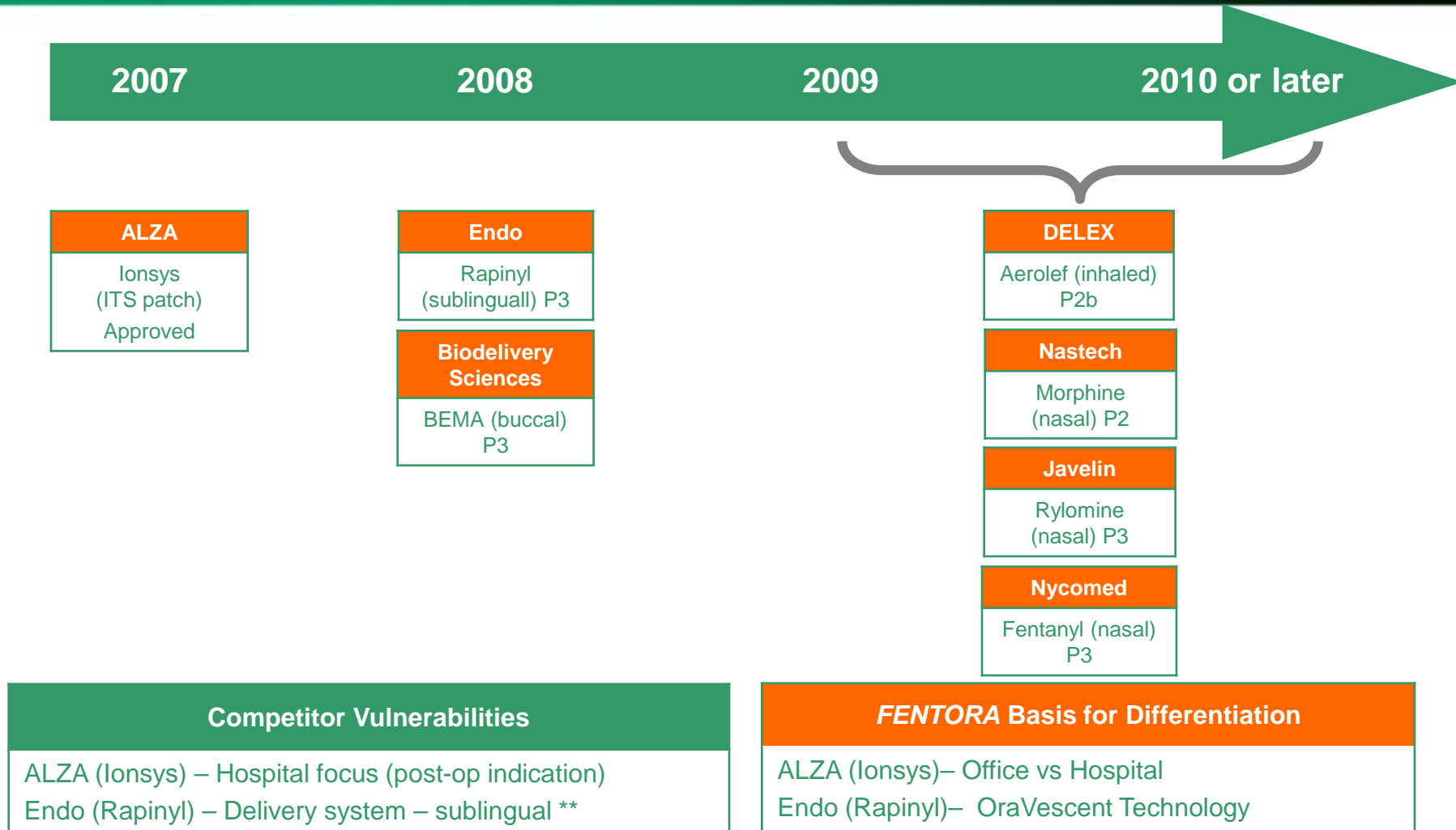
	2005 Pain Sales (US)	Primary Focus	Pain Products	Potential to Lead in Future
<b>Purdue</b>	\$1.4B	Pain Care	OxyContin (\$1.36B), MS Contin (\$32M), Palladone (\$20M)*, OxyIR	Reputation suffers due to OxyContin issues and Palladone withdrawal
<b>J&amp;J</b>	\$1.4B	Primary Care	Duragesic (\$687M), Ultracet (\$145M), Ultram (\$37M), Ultram ER*	Part of corporate strategy is to re-focus efforts in pain, developing new business unit
<b>Endo</b>	\$1.2B	Pain Care	Lidoderm (\$573M), Percocet (\$122M), Depodur, Opana, Opana ER, Additional generic opioids (\$370M)	Potential to lead in the future due to single focus in Pain Category
<b>King/Ligand</b>	\$179M	Oncology, Pain Care	Avinza (\$179M)	Strong presence in LAO market with a focus on TR (Remoxy)
<b>Alpharma</b>	\$140M	Pain Care	Kadian (\$140M)	Limited product portfolio

\* Pulled from market due to alcohol risk  
Source: IMS 2006

# Product Pipeline

Company	Phase I-II	Phase III	Reg. – Approval
J&J <ul style="list-style-type: none"> <li>Alza</li> <li>OMP PriCara</li> </ul>		Oros Hydromorphone Tapentadol	Ionsys (Fentanyl Iontophoretic Transdermal System) – Approved May 2006
Endo	Lidoderm (chronic LBP) LidoPAIN (acute LBP) Chronogesic(Chronic moderate to severe pain) Ketoprofen patch Hydrocodone/paracetamol/dextromethorphan Oxycodone/dextromethorphan Oxycodone/paracetamol/dextromethorphan Sufentanil – DURECT Morphine/dextromethorphan	Rapinyl (BTP in cancer patients)	
Forest	Memantine Neramexane RGH-896	Milnacipran	
Purdue			Tramadol XR
BioDelivery Sciences		BEMA Fentanyl	

# ROOs in Development



Note – not all product in development are expected to launch

\* 30 minute onset of action. Not a ROO

\*\* No effervescent reaction

Source: Cephalon Market Research



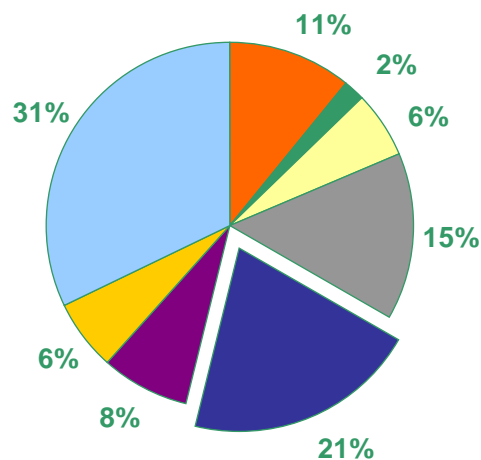
# Share of Voice

Rank	Pain	PCP
Depodur	1 <sup>st</sup>	8 <sup>th</sup>
Actiq	2 <sup>nd</sup>	5 <sup>th</sup>
Kadian	3 <sup>rd</sup>	4 <sup>th</sup>
Avinza	4 <sup>th</sup>	1 <sup>st</sup>
Duragesic	5 <sup>th</sup>	6 <sup>th</sup>
OxyContin	6 <sup>th</sup>	3 <sup>rd</sup>
Other	7 <sup>th</sup>	7 <sup>th</sup>
Combunox	8 <sup>th</sup>	2 <sup>nd</sup>

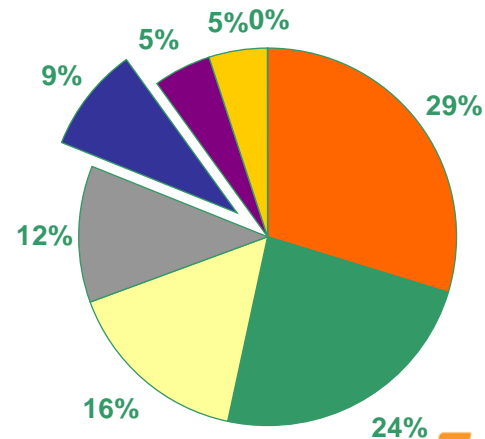
## Opioid Sales Calls (Q1 06)

- Actiq has a significant SOV in the Pain specialty (ranked 2nd vs. LA Depodur ) market segment
- The branded LAOs represent the greatest SOV in the PCP segment (approximately 63%) while Actiq SOV was limited to 9%

### Pain Specialists



### Primary Care



# Market Situation

## Market Environment

**FENTORA<sup>TM</sup>**  
*fentanyl buccal tablet* ®

# Key Environmental Trends

## Key Factors

**Economic**

**Social / Cultural**

**Political /  
Governmental**

**Legal**

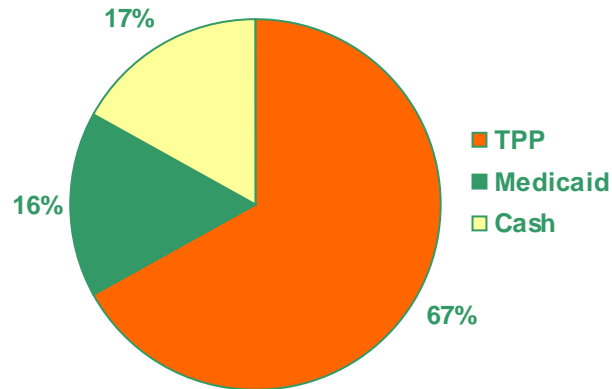
**Clinical /  
Technological**

## Current Dynamics

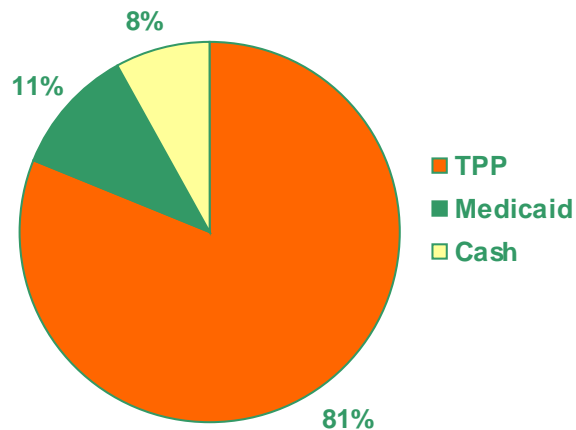
- Unfavorable reimbursement environment
- Payers are increasing restrictions to drive usage to less costly drugs
- Payers don't understand BTP
- Abuse and diversion are top-of-mind topics for physicians and other stakeholders
- Society (including many physicians) are critical of their patients' inability to cope with their pain
- Pain patients feel misunderstood by physicians, friends, and family and often become frustrated and depressed
- Patients are often looking for an easy short-term solution to their pain and are not focused on long-term wellness
- Opioid abuse is a hot political issue and physicians are under significant scrutiny about proper use of opioids
- FDA is hypersensitive about safety issues in a post-Cox II and OxyContin world
- DEA guidelines for writing opioids are unclear
- Ongoing issues between the DEA and various pain societies
- Perception that more physicians getting sued/licenses taken away
- Lack of significant practical advancements in pain medicine
- New drugs, routes of administration, and improved control of side effects
- New insights into the anatomy and physiology of pain perception
- Greater understanding of how to integrate pharmacotherapeutic, psychological, and behavioral pain management approaches
- New tracking technology for packaging to avoid diversion

# Economic

## Pure SAO (w/o Actiq) Reimbursement



## ROO (Actiq) Reimbursement



## Reimbursement

- Opioid market is highly genericized
- Vast majority of Pure SAOs & ROOs covered by TPP
- *FENTORA* more apt to have TPP reimbursement barriers due to its premium price
  - Tiered co-pays, co-insurance, PAs, step-edits, qty limits, dose limits
- Overall Pure SAO class has slightly greater share of Medicaid reimbursement compare to ROO sub-class

# Social: BTP Awareness

## Prescribers

- BTP is a relatively new disease state, only generally recognized by top tier opioid prescribers
  - First in print in 1990 (Portenoy survey)
  - Actiq first product indicated for BTP, launched 1998

## Patients

- Do not recognize term “Breakthrough Pain”

# BTP Communication

Topic	Physician*	Patient**
BTP Terminology	If BTP discussed, use “BTP” and “pain flares” interchangeably	Don’t use “BTP”, describe pain as “uncontrolled” or use descriptive terminology (e.g., flares, burning)
Quality of Life	Treatment success reported by patient in terms of function or activity	<ul style="list-style-type: none"> <li>• Focus on holistic impact on life</li> <li>• E.g. emotion, personality, social, &amp; function</li> </ul>
Fear	<ul style="list-style-type: none"> <li>• Patient abuse, addiction, &amp; diversion of opioids</li> <li>• Regulatory scrutiny</li> </ul>	<ul style="list-style-type: none"> <li>• Addiction (loss of independence)</li> <li>• Over medication (sedated / confused)</li> <li>• Running out of opioids (rationing)</li> <li>• Anxiety over severity and timing of next BTP episode (unpredictability)</li> <li>• Physicians will stop prescribing opioids</li> </ul>
Communication of Pain	Distance themselves from chronic pain patients	Hold back communicating full impact of pain

# Market Drivers BTP Market

## Growth Drivers

- Aging baby boomers and growing US population will increase the size of the chronic pain patient population
- Increase in treatment of chronic pain with opioids
- Pain Specialists are more aggressive in treating chronic pain
- More sophisticated usage of opioids by PCPs who continue to drive the majority of opioid TRx volume
- Increasing understanding about the proper identification, diagnosis and treatment of BTP
- New competitive entries

## Growth Inhibitors

- Scrutiny from regulators and general confusion on the part of key stakeholders fuels concern about the abuse, addiction, and diversion of opioids
- Due to the widespread availability of generics in the opioid market, managed care has placed significant restrictions on the use of branded opioids
- Chronic pain practice standards (especially for BTP) are still evolving
- Physicians believe that increasing the dose or dosing frequency of LAOs can adequately cover a BTP episode while ignoring the effects of overmedication [influenced by Purdue and Janssen]
- Perception by some physicians that SAOs are a preferred treatment option for BTP based on familiarity, ease-of-use, and cost

# Summary

- The chronic pain opioid market remains attractive because of its substantial size and growth
  - Pure SAOs – highest growth rate (TRx +21%, \$ +23%)
  - Combination SAOs – dominate volume (83% TRx market share)
  - LAOs – dominate market value (68% \$ market share)
- Generic expirations of blockbuster brands (ie, Duragesic, OxyContin) has resulted in a promotional void in the pain market
- Innovative drug delivery technology is the foundation of recent successful brands and drugs in the later stage of development



# Summary

- BTP remains an untapped market
  - Physicians rely heavily on LAOs when addressing patients' BTP
  - Physicians also utilize generic SAOs due to familiarity, ease of use and cost
  - Even among high-users of Actiq, SAOs remain the treatment standard for BTP
- For the treatment of BTP, a communication gap exists between physicians and patients
- Concerns over opioid misuse and reimbursement hurdles continue to be key barriers to utilization
- The pain specialist continues to be the key market segment for new brand adoption
- Several new formulations of ROOs are in development and should come to market over the next 1-5 years helping to solidify this emerging sub-class of opioids

# Product Situation

## Profile & Position

***FENTORA***<sup>TM</sup>  
*fentanyl buccal tablet* ®

# FENTORA Description & Indication



## Description

*FENTORA*, which employs the OraVescent® drug delivery technology, is a potent opioid analgesic, intended for buccal administration. *FENTORA* is formulated as a flat-faced, round, beveled-edge tablet.

## Indication

*FENTORA* is indicated for the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain



**FENTORA**

# Product Profile Comparison

Attributes		FENTORA	Actiq
Indication		Launch: BTP in patients w/ Ca 2008: BTP in non-Ca patients	BTCP
Efficacy	Onset	15 min (99-14) 10 min + “meaningful relief” (3039)	15 min
	Duration	60 min (99-14) 120 min (3039)	60 min
PK (FENTORA 400 mcg vs Actiq 800 mcg)	Absolute Bioavailability	65%	47%
	Transmucosal Absorption	48%	22%
	Cmax (mean ng/mL)	1.02	1.26
	Tmax (median, min)	46.8	90.8
Administration	Convenience	Discreet tablet	Lozenge on a stick
	Ease of Use	Passive administration	Active administration
	Dosage	Launch: 100, 200, 400, 600, 800 mcg sNDA: 300 mcg In development: higher dose	200, 400, 600, 800, 1200, 1600 mcg
	Titration	Multiple 100 & 200 mcg tablets	1 higher strength at a time

# FENTORA

## Product Profile Comparison

Attributes		FENTORA	Actiq
Safety	AE Profile	Comparable to other opioids (except for application site abnormalities)	Comparable to other opioids (except for application site abnormalities)
	Abuse Potential	Comparable to other opioids	Comparable to other opioids
	Accidental Exposure	Comparable to other opioids	Lozenge on stick presents potential concerns: <ul style="list-style-type: none"> <li>– Pediatric exposure</li> <li>– Partially used unit exposure</li> </ul>
Formulation		Sugar-free	Sugar

# FENTORA

## Product Profile Comparison

Features/Benefits	<i>FENTORA</i>	Actiq	SAOs
Efficacy – Onset	+++	++	-
Efficacy – Duration	++	++	+
Convenience	++	+	++
Ease of Use	+	-	++
Ease of Titration	+	-	++
Side Effect Profile	+	-	++
Abuse Potential	-	-	-

Sources: TrialZ Study, Jan 2005 (Conjoint Study).  
MDS Study, Dec 2004

# FENTORA Product Profile:

## Physician Reactions

### Physician Perception of *FENTORA*

Drivers	Barriers
<ul style="list-style-type: none"> <li>• Faster onset of pain relief</li> <li>• Overall efficacy</li> <li>• Convenient administration</li> <li>• Ease of use (vs IV administration)</li> <li>• Sugar-free</li> <li>• Unique delivery system</li> <li>• Utilizes less fentanyl</li> <li>• Discreet (ie, no handle vs Actiq)</li> </ul>	<ul style="list-style-type: none"> <li>• Anticipated high cost (reimb. hassle)</li> <li>• Potential for abuse</li> <li>• Potent opioid (held in reserve)</li> <li>• No handle administration*               <ul style="list-style-type: none"> <li>– Actiq saves \$ with partial dosing</li> <li>– Perception Actiq can be removed if S/Es</li> </ul> </li> </ul>

- Overwhelmingly, the majority of physicians expressed an interest in this product and felt it had a place in their practice

\* Contrary to Actiq PI (physicians perception)  
Source: Summary of Market Research Q4 04 – Q1 06

# Position & RTB

## Position Statement

*FENTORA* is the first and only fentanyl buccal tablet which utilizes an effervescent reaction to provide the most ***rapid onset of analgesia*** of any oral opioid, resulting in improved patient functioning and activities of daily living.

## Reason to Believe

*FENTORA* employs the ***OraVescent® drug delivery technology***, which generates a reaction that releases carbon dioxide when the tablet comes in contact with saliva<sup>1,2</sup>

- It is believed that transient pH changes accompanying this reaction may optimize dissolution (at a lower pH) and membrane permeation (at a higher pH)



# Messaging (*Vanilla at Launch*)

- Onset of pain relief within 15 min in some patients (1<sup>st</sup> time pt measured)
- Duration of pain relief up to 60 min (last time pt measured)
- OraVescent drug delivery technology may optimize delivery of fentanyl across the buccal mucosa
- Fentanyl is readily absorbed, achieving an absolute bioavailability of 65%
- AEs comparable to other opioids, except for application site abnormalities (8%)
- Convenient, discreet, and sugar-free tablet

## Note:

- 99-14 data only included in label at launch

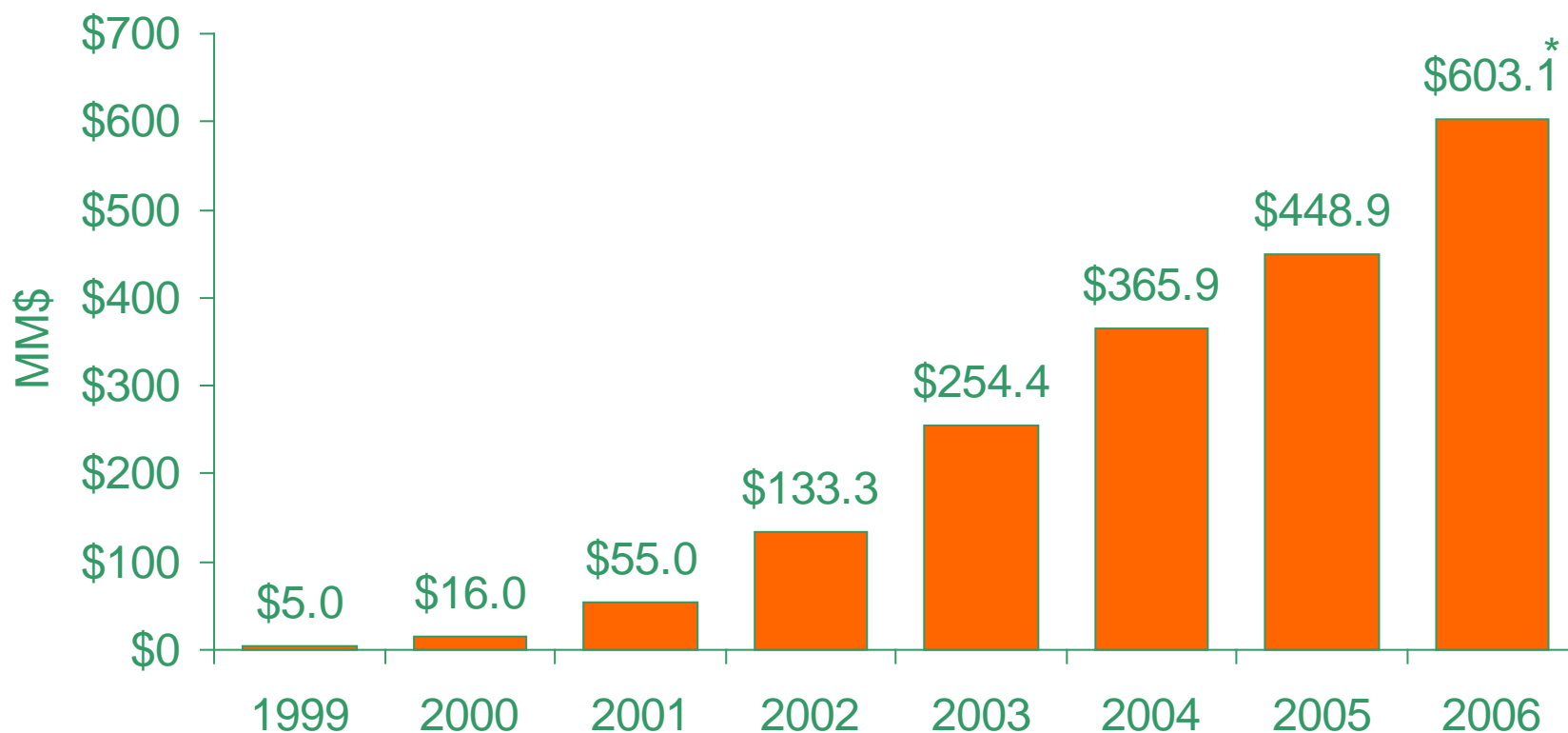
# Product Situation

## Actiq Performance

**FENTORA<sup>TM</sup>**  
*fentanyl buccal tablet* ®

# Actiq Gross Sales

- Actiq continues growth in Sales



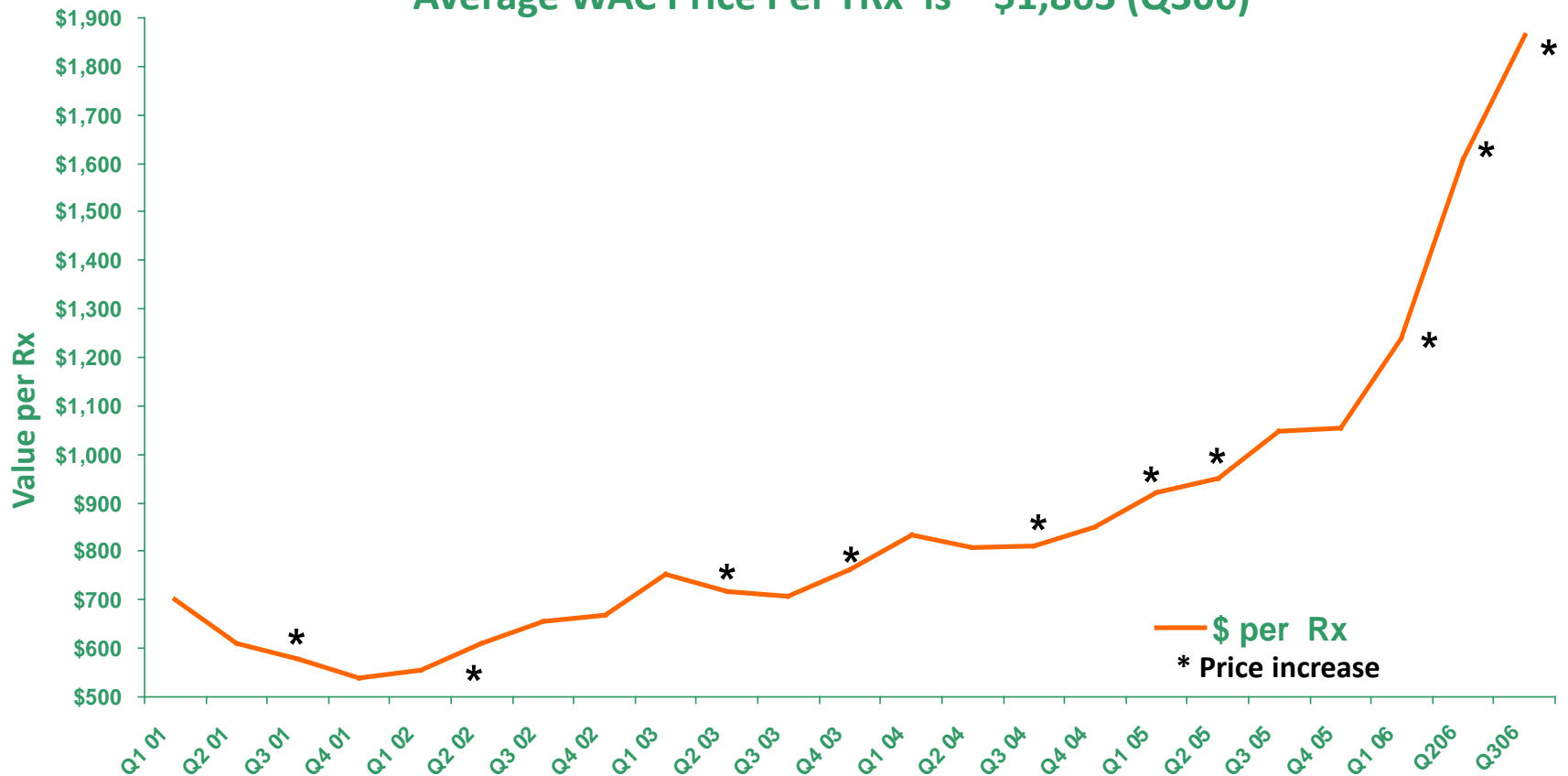
Source: Internal shipment data

\*Actuals through 10/06,  
11,12/06: per 9+3 forecast

# Actiq Pricing

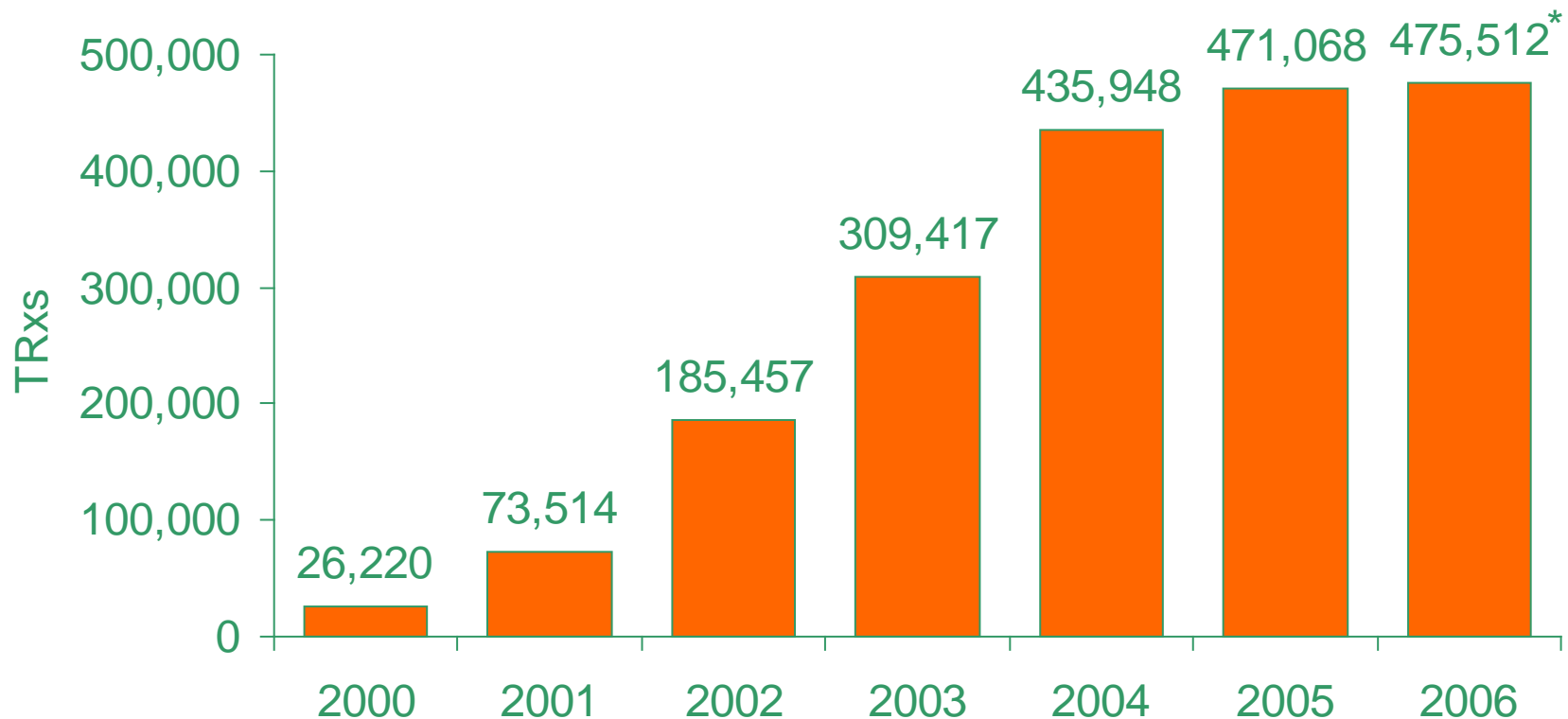
- Price increases have aided revenue growth

Average WAC Price Per TRx is ~ \$1,863 (Q306)



# Actiq TRxs

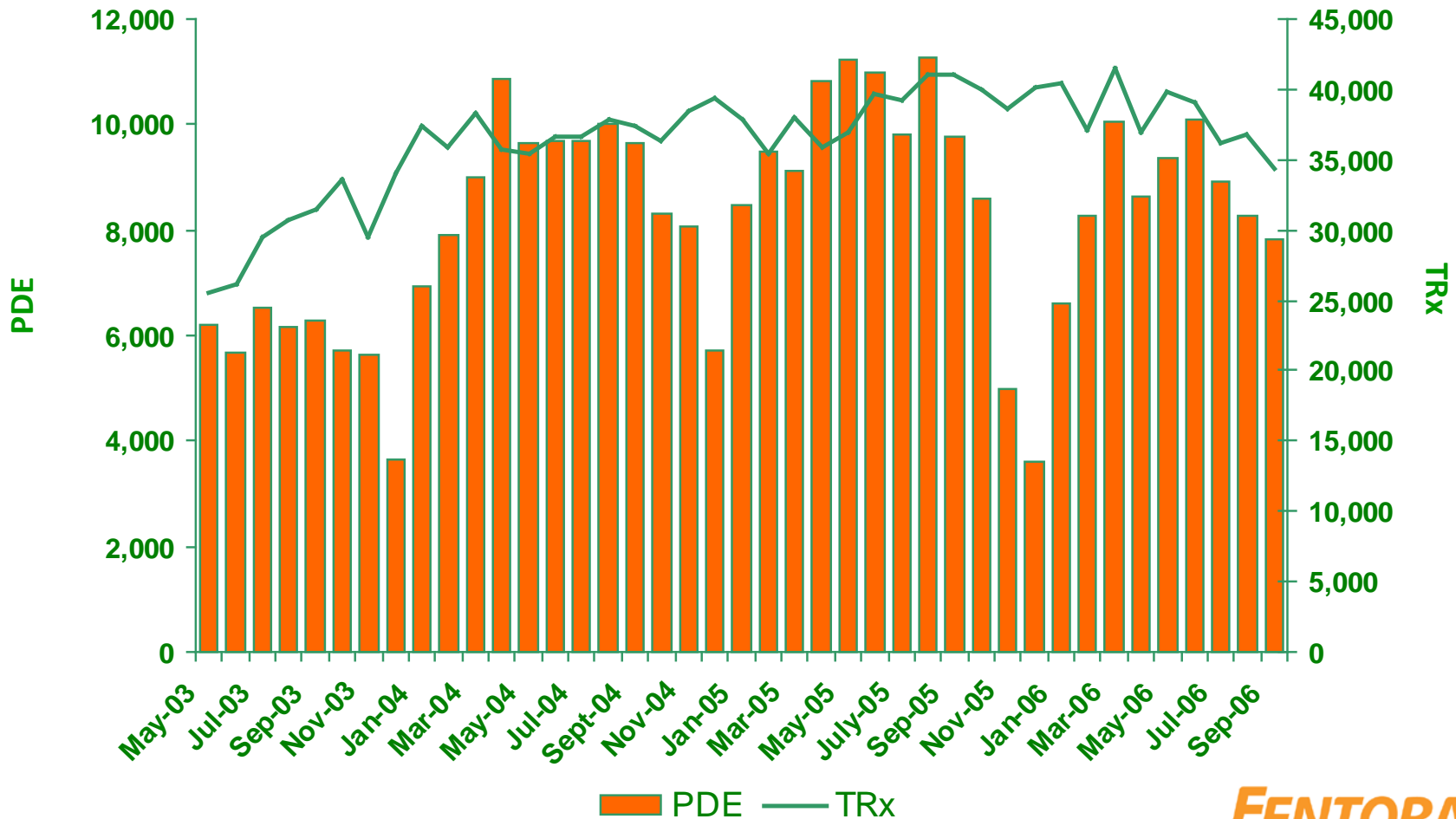
- Actiq has performed beyond expectations despite limited data
- Field Force has been able to maintain TRx volume



Source: IMS NPA

\* Actuals through 10/06,  
11,12/06: per 9+3 forecast

# PDEs\* & TRxs



■ PDE — TRx

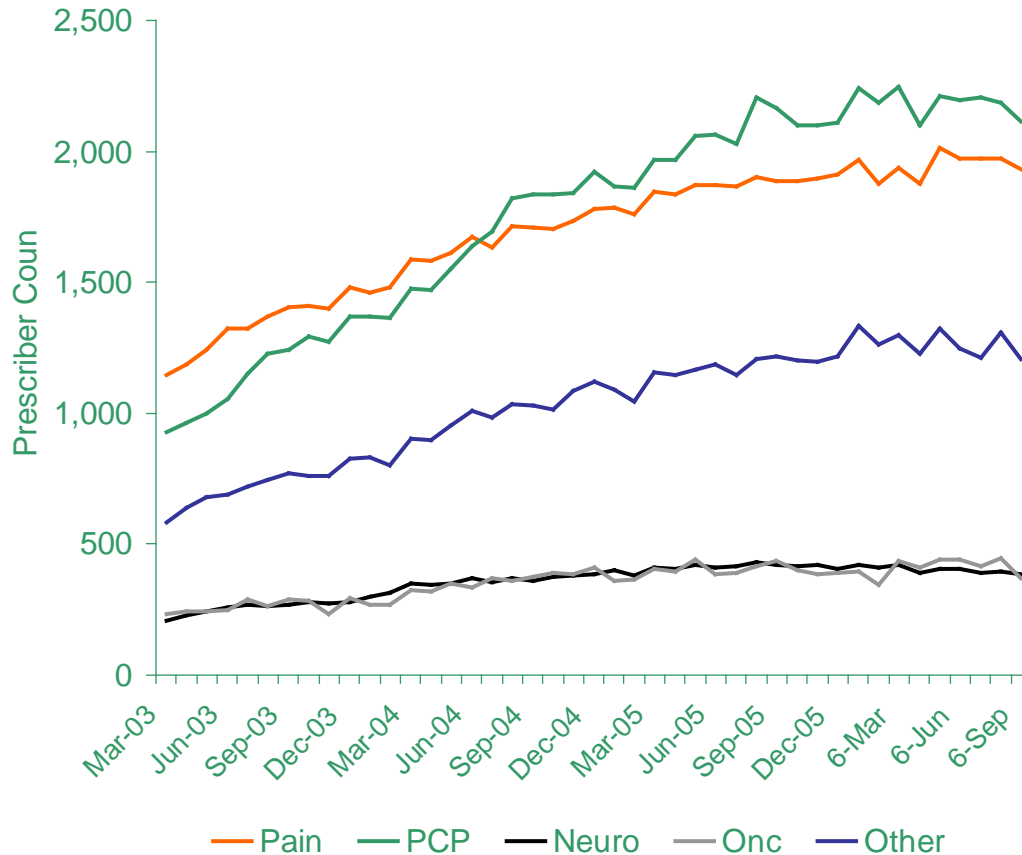
**FENTORA™**  
fentanyl buccal tablet @

\* 11/05 and 12/05 PDE data does not include any of the detailing from the Oncology Sales Force  
Source: IMS NPA & SMART Call File

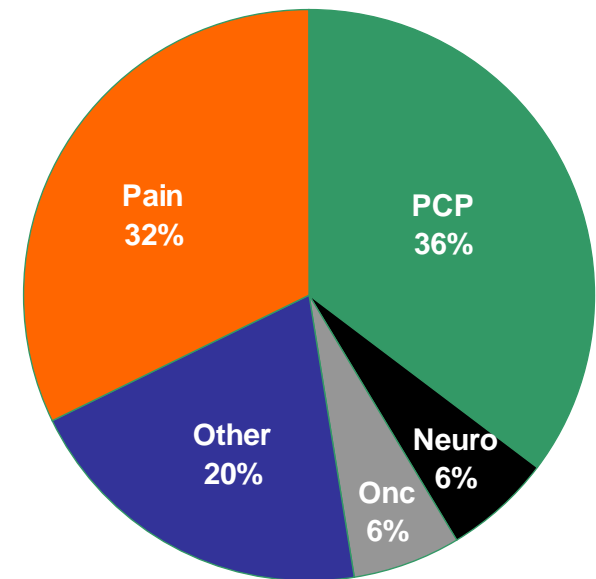
# Actiq Monthly Prescriber Count by Specialty\*

Case: 1:17-md-02804-DAP Doc #: 2557-18 Filed: 08/30/19 47 of 150 PageID #: 411854

- PCPs continue to outnumber Pain Specialists



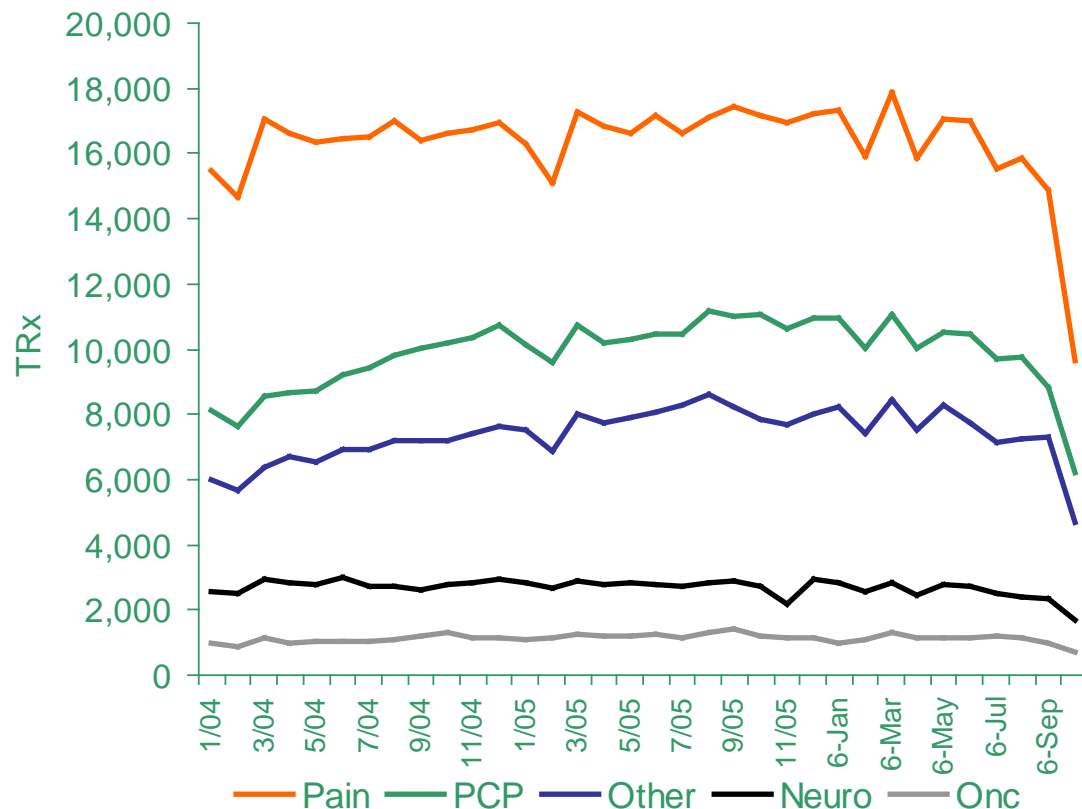
September 2006



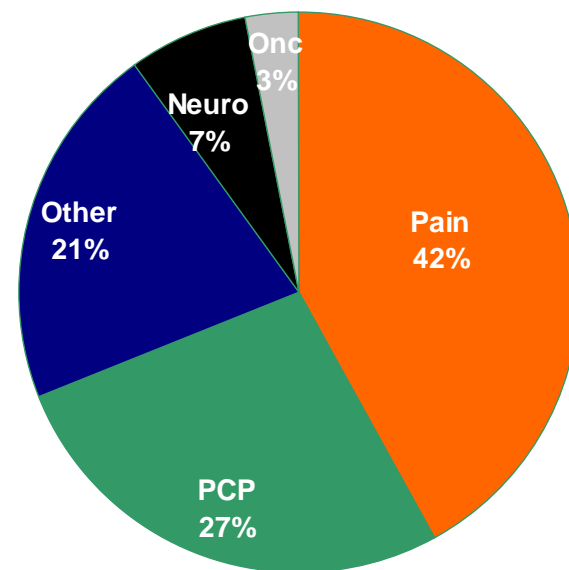
\* Cephalon defined Specialty Group  
Source: NDC

# Actiq Monthly TRx by Specialty\*

- Pain Specialists continue to write majority of prescriptions



October 2006



Cephalon defined Specialty Group  
 \* Anesthesiology, PM&R and Pain  
 Source: IMS NPA

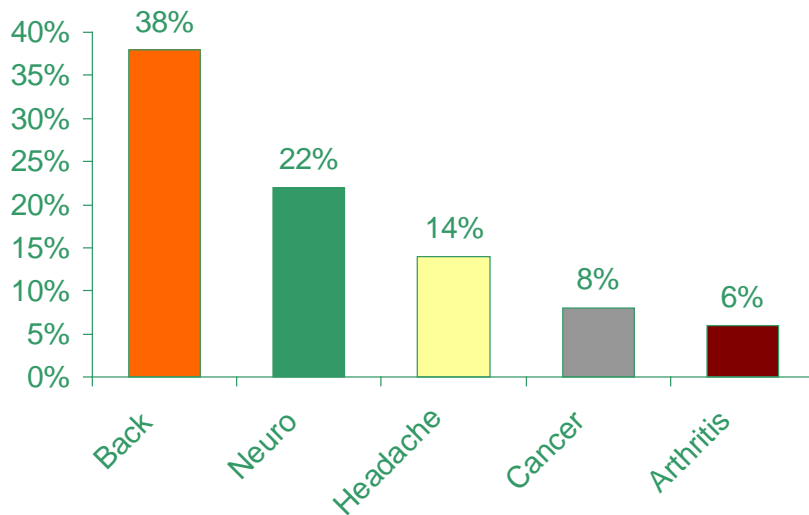


# Conditions Treated with Actiq

- Despite promotion in BTCP, Actiq use mirrors that of all opioids

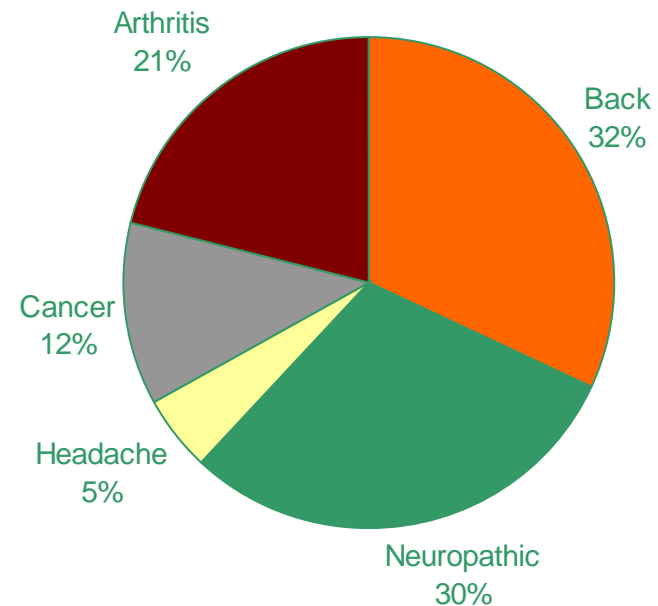
## Underlying Conditions Treated with Actiq

N=774 Patients



## Chronic Pain Patients Treated with Opioids

Estimate – 2.8 M Patients



# Product Situation

## ***FENTORA*** Performance

***FENTORA***<sup>TM</sup>  
*fentanyl buccal tablet* ®

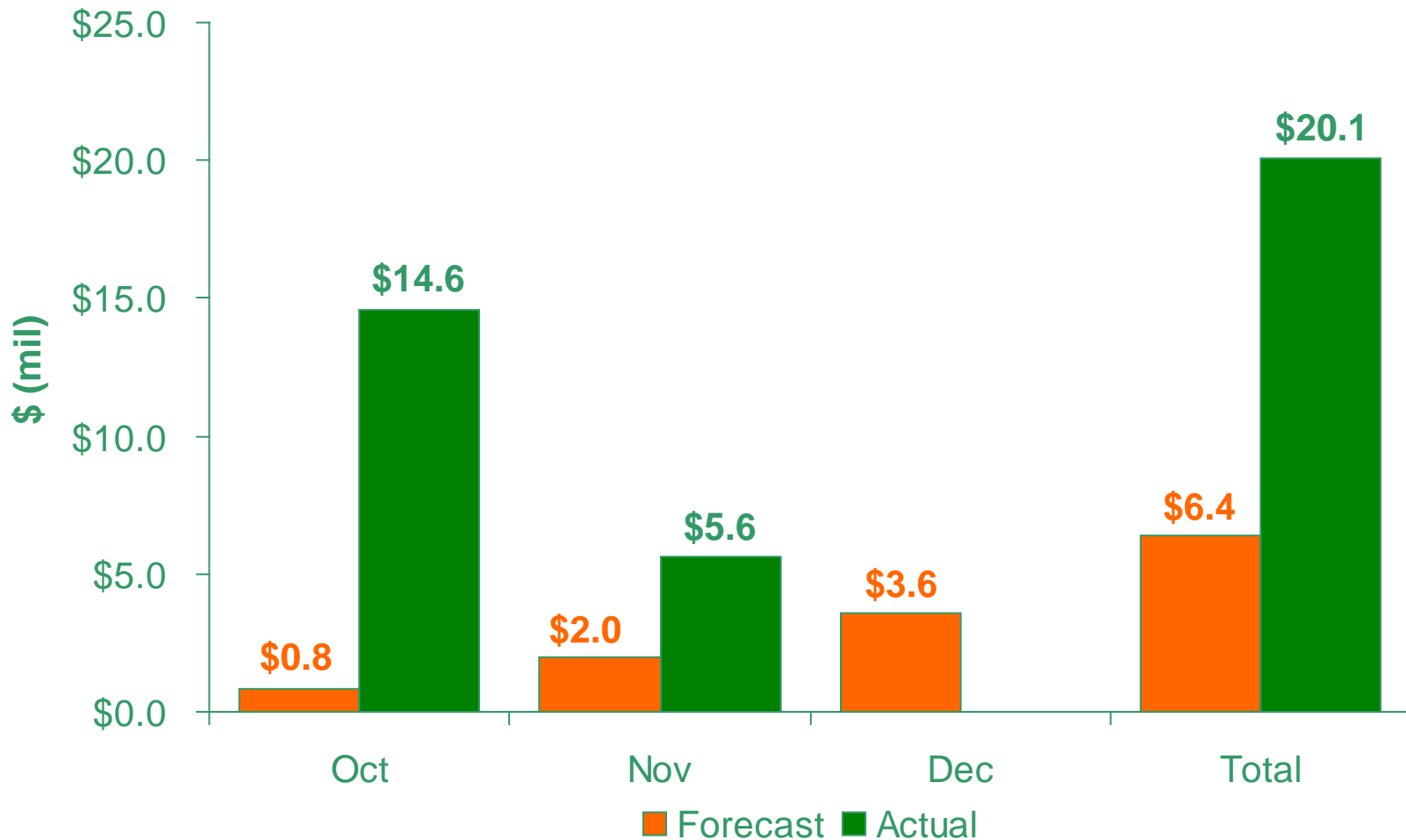
# Product Availability

- Initial supply chain hiccups (resolved quickly)
- Currently stocked in ~1,400 pharmacies
  - ~13% of the number of pharmacies stocking Actiq (11K)
  - Initial stocking more in independent pharmacies

# FENTORA Shipments

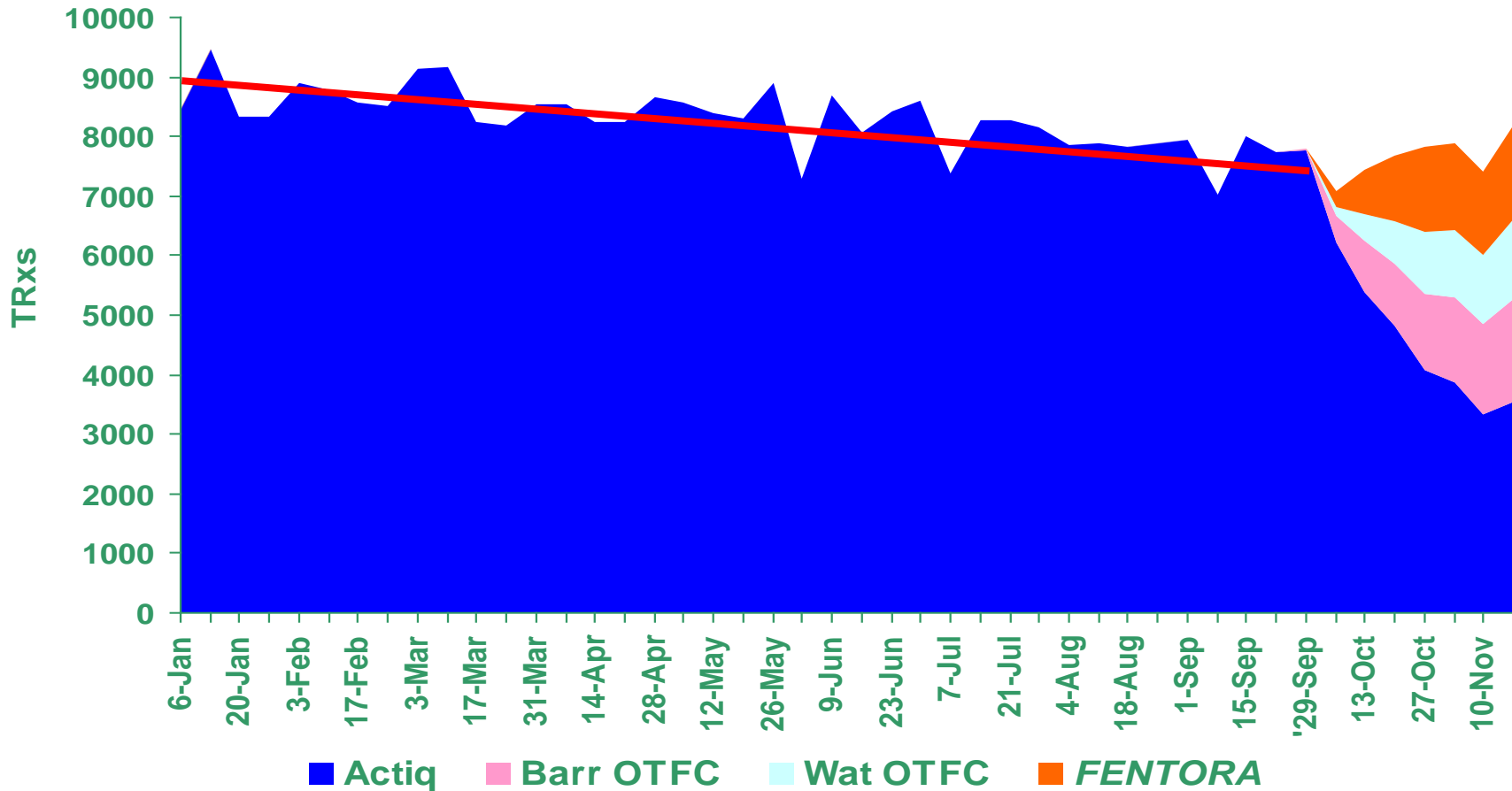
## Forecast vs Actual

**FENTORA Shipments (\$20M YTD 11/16, 315% of Tot '06F)**



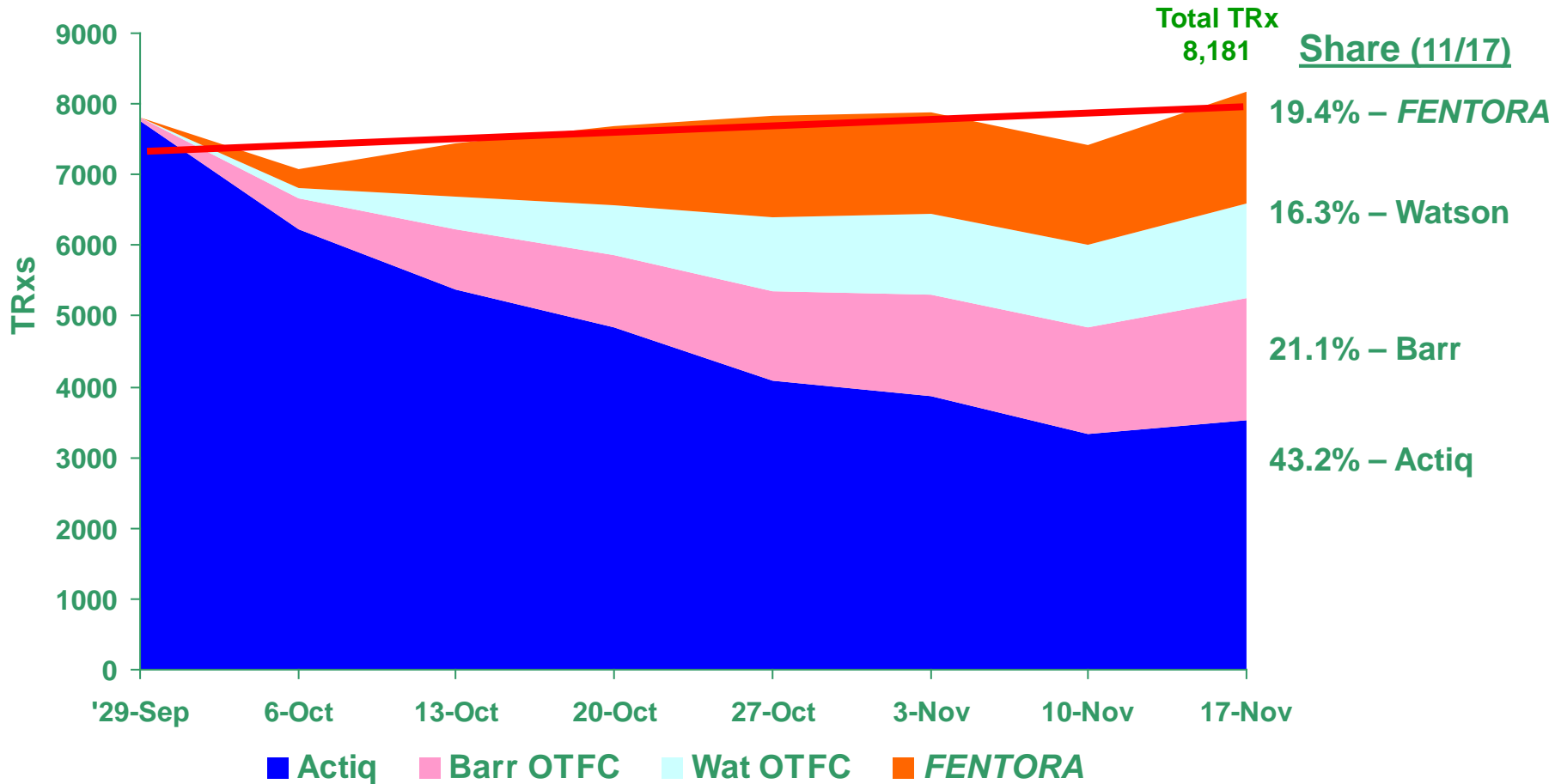
# ROO Weekly TRxs

## As of 11/17/06



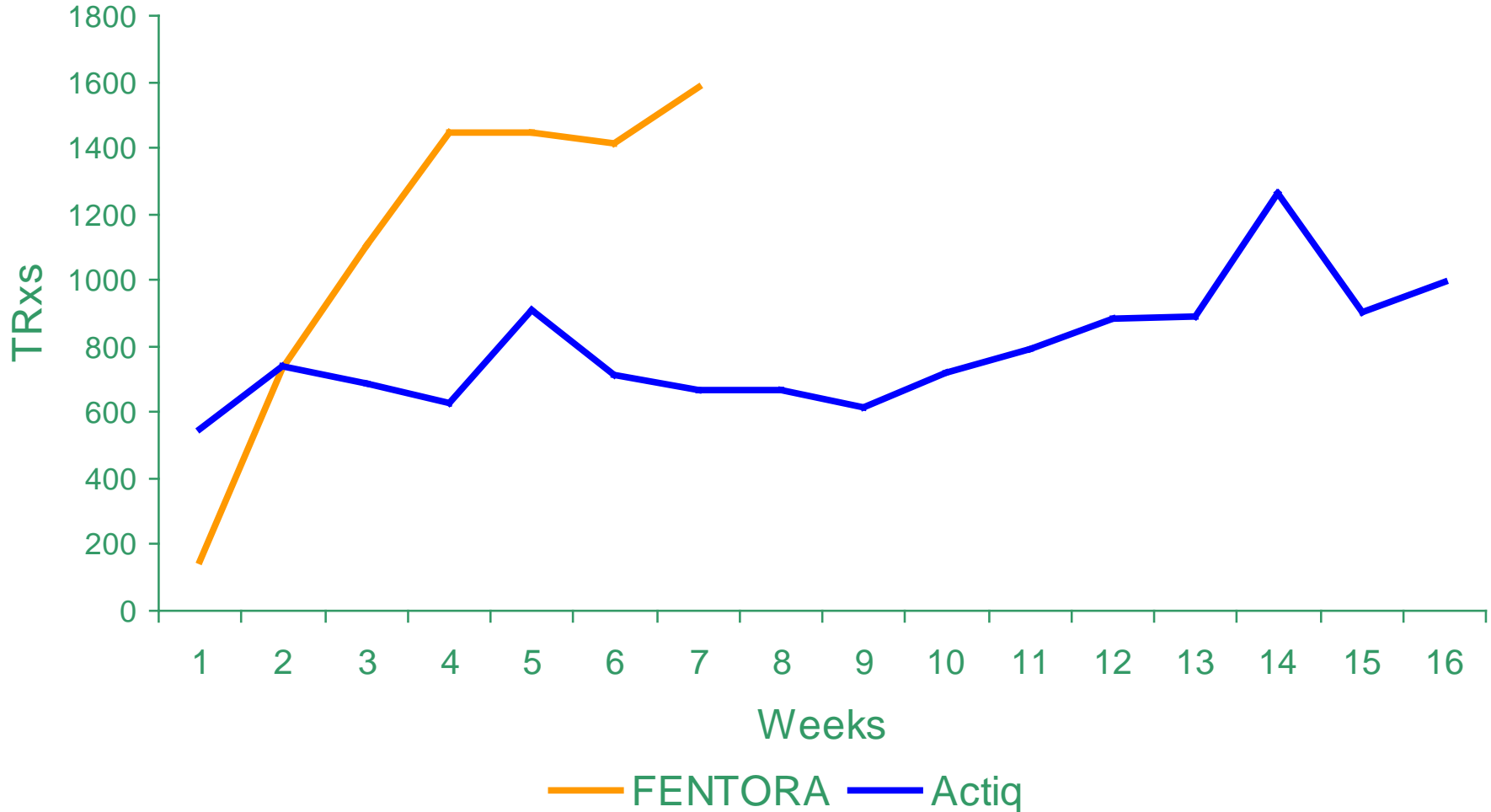
# ROO Weekly TRxs

## As of 11/17/06



# FENTORA vs. Actiq\*

## Weekly TRxs

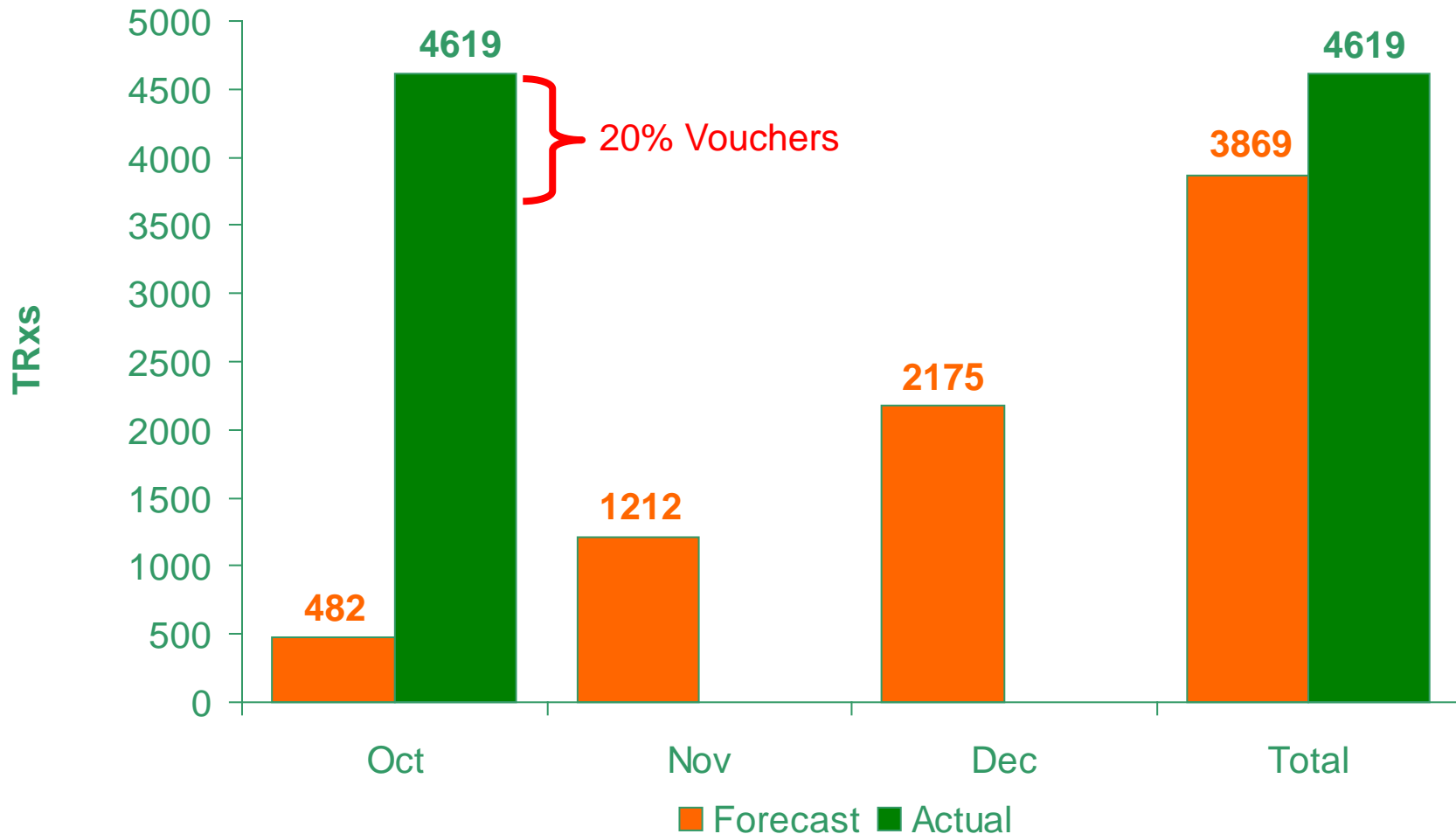


\*Actiq weeklies are from Cephalon re-launch (April 2001)

# FENTORA TRxs

## Forecast vs Actual

### FENTORA TRxs (119% of Tot '06F)

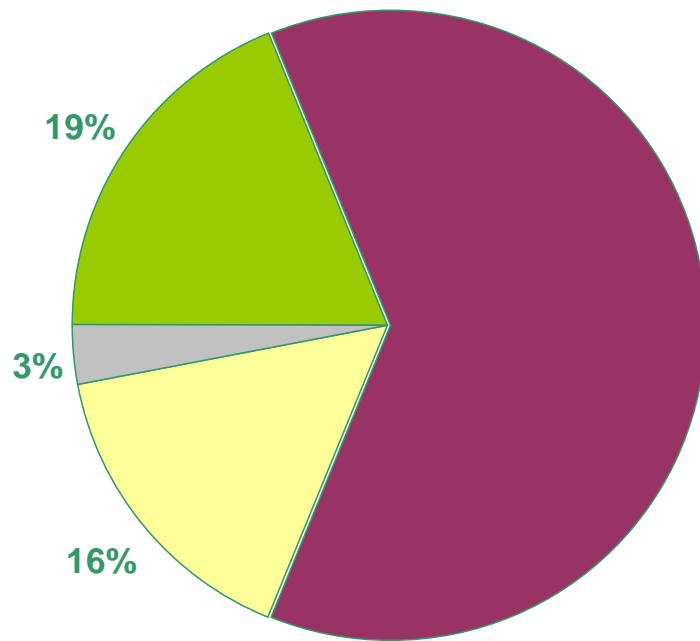




# FENTORA TRx Origin

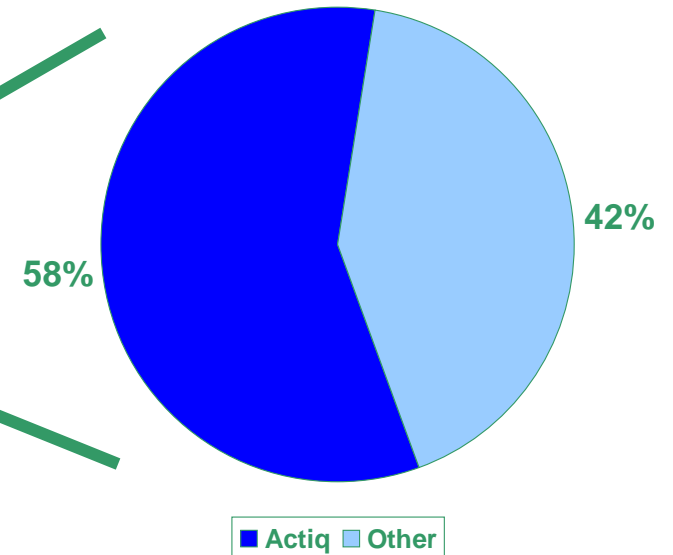
## Sum of weeks 10/06 – 11/10

TRx Source



62%

TRx Switch



58%

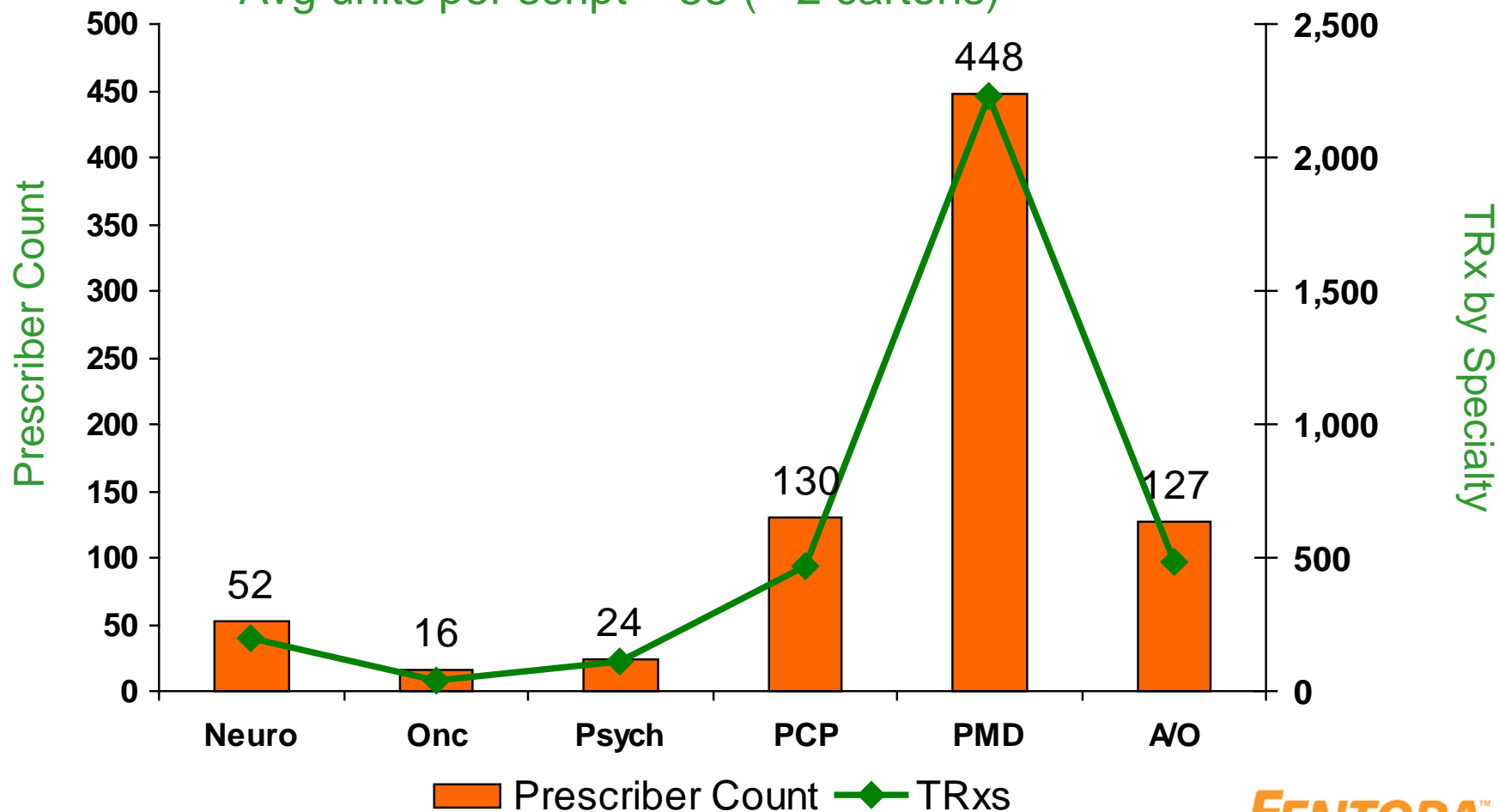
42%

■ New ■ Switch ■ Continuation ■ Unclassified

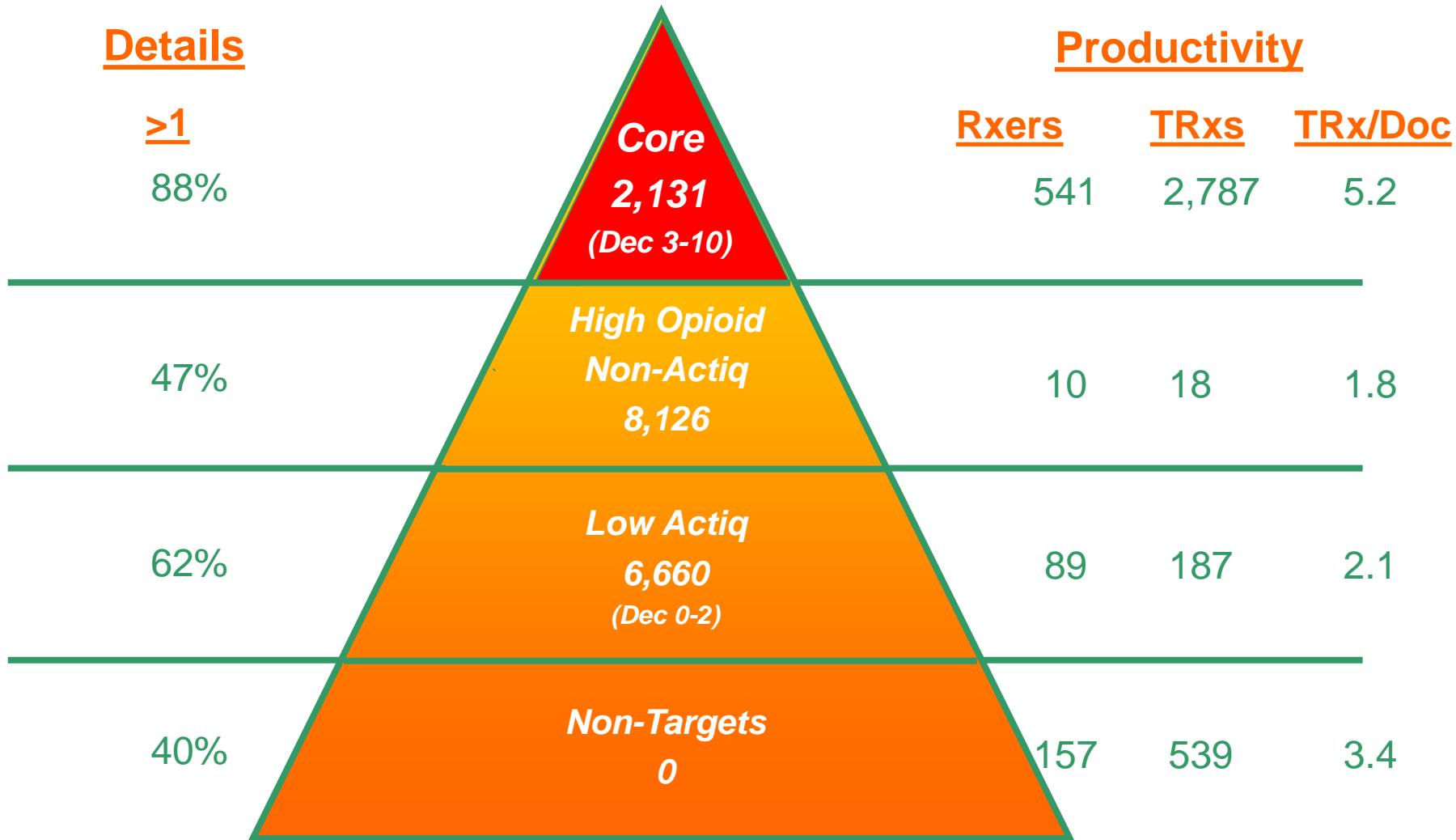
■ Actiq ■ Other

# Specialty Count & Productivity

- Pain Specialists are early adopters driving TRxs
- Avg units per script = 55 (~ 2 cartons)



# TRx by Targets

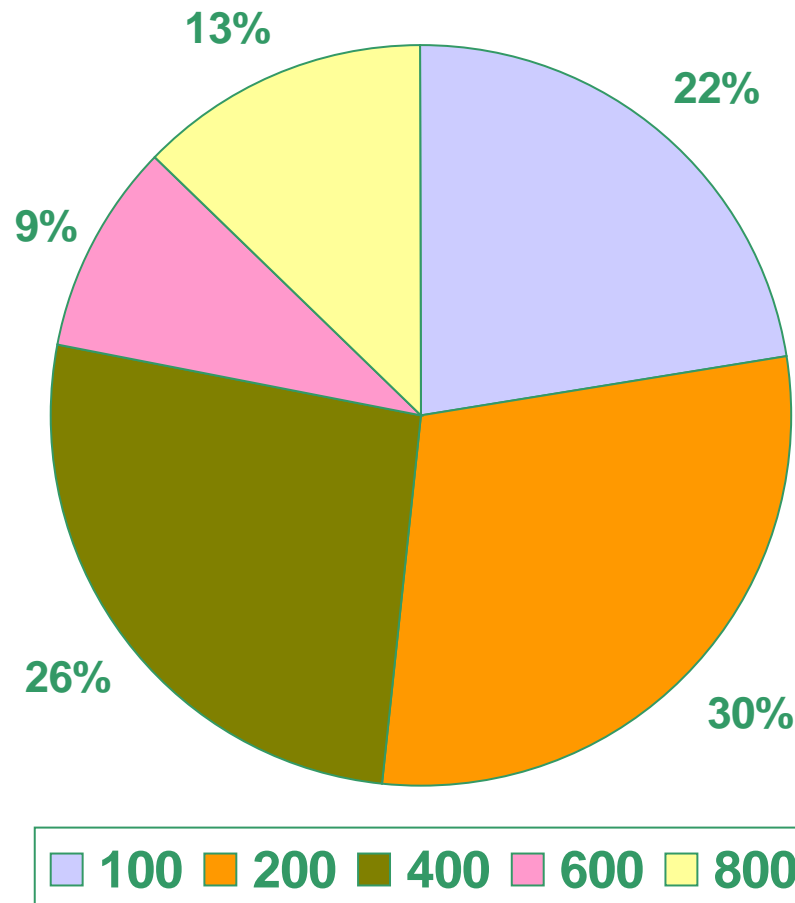


# Field Activity

- Cephalon Speaker Programs (CSP)
  - 284 Speakers Trained (148 E & 136 W)
  - FENTORA YTD (2 mos) – 781 completed, 271 pending
    - Reach YTD: 5,570 attendees (non-Cephalon)
    - Reach Pending: 1,700
  - Actiq YTD – ~ 400/qtr
- October vouchers
  - 942 redeemed
  - 20% of TRxs

# Vouchers by Strength October

Total vouchers redeemed: 942



Source: NDC October 2006

# SWOT & Key Issues

**FENTORA<sup>TM</sup>**  
*fentanyl buccal tablet* ®

# FENTORA SWOT Analysis

## Strengths

- Onset of analgesia 10 min
- Duration of analgesia 120 min
- Discreet and convenient dosing formulation
- Predictable bioavailability vs. Actiq
- Efficient drug delivery (65% absolute bioavailability)
- Easier dose titration scheme than Actiq
- Data on Actiq to *FENTORA* switch
- Clinical program to expand label
- Patent on *FENTORA* through 2019
- Published data in non-cancer BTP

## Weaknesses

- C-II abuse and diversion potential
- Cost vs. other SAOs (branded and generic alternative therapeutic options)
- Reimbursement restrictions
- Limited label (BTP in cancer patients) at launch and potentially up to 3 years post-launch due to carcinogenicity study
- Perceived safety concerns of fentanyl due to misunderstanding of potency and equianalgesic conversion (mg vs. mcg)
- Cephalon not a lead player in pain market
- Current sales force size limits ability to expand into new market segments, e.g., broader audience, hospitals, etc.

# FENTORA SWOT Analysis

## Opportunities

- KOL eagerness to evaluate and establish standards for treatment guidelines for BTP
- Increased focus on pain management from JCAHO (5<sup>th</sup> vital sign) and NIH (Decade of pain Control and Research)
- Though limited, there is some increasing awareness and understanding of BTP
- Concentrated Actiq prescriber base enables for focused targeting
- Limited number of promoted products within the market segment (SOV)
- Aging population
- Opportunity to develop outcomes data for BTP (burden of illness)

## Threats

- Limited understanding of BTP and its appropriate management outside a small community of pain specialists
- Fear of abuse and diversion with opioids
- Increasing government restrictions on C-II opioids
- Generic SAOs
- Generic OTFC
- Published data for Actiq vs. IV morphine documenting median time for pain relief 4.2 minutes
- Managed care and other third-party payers (including Medicare Part D and Medicaid) increasing their efforts to restrict high-cost drug use
- Competitive pricing pressure
- Treatment guidelines include competitive products, e.g. Actiq, SAOs
- Emerging ROO pain formulations (e.g., Rapinyl)



# Key Issues

- Third Party Payers manage costs by placing reimbursement limitations/restrictions on premium priced therapies
- Limited number of health care providers prescribe a ROO for BTP
- FENTORA is not clearly differentiated from other BTP and non-BTP treatment options
- Physicians and patients have limited understanding about the appropriate diagnosis and treatment of BTP; a contributing factor is the communication disconnect between physicians and patients in regards to pain
- Anticipated dosing and administration challenges for both physicians and patients
- Risk for abuse, addiction, and diversion
- Limited KOL and professional society relationships impact peer-to-peer knowledge and uptake of FENTORA

# Where We Are Now

**Today's Objective:  
Commercial Alignment**

***FENTORA***<sup>TM</sup>  
*fentanyl buccal tablet* ®

# Where we are now

- Product Uptake: initial trial & utilization by Actiq loyalists
- Product Profile: Little more than Actiq without a stick
  - Launch Promotional Package – PK Story, Sugar Free
- Goal: Lay the groundwork to expand the product profile & position FENTORA as the gold standard BTP product beyond Actiq loyalists
- Today's Objective: Establish commercial alignment in laying the foundation for the future

Where we're going

**Marketing Strategy**

***FENTORA***<sup>TM</sup>  
*fentanyl buccal tablet* ®

# Marketing Strategy

## Mission & Strategic Vision

***FENTORA***<sup>TM</sup>  
*fentanyl buccal tablet* ®

# Mission

## Franchise Mission

Establish Cephalon as a major player in pain management

## FENTORA Mission

Establish FENTORA as the gold standard for BTP

# Three Year Strategy

What *FENTORA* Should Be: The optimal solution for BTP

Brand Essence: Effervescent speed

Differentiate from existing options

Receptive to *FENTORA* profile

Willing to try *FENTORA* in select BTP patients

Using *FENTORA* routinely in select BTP patients

Routine use of *FENTORA* to treat BTP in a broader population

*FENTORA* is viewed as the optimal therapy for BTP vs Oxy IR and other SAOs

Reducing use of ATC medications while maximizing benefits of *FENTORA*

2007 - 2008

2008 - 2009

# Three Year Strategy

What *FENTORA* Should Be: The optimal solution for BTP

Brand Essence: Effervescent speed

Reinforce and promote routine use



2007 - 2008

2008 - 2009



# Three Year Strategy

What *FENTORA* Should Be: The optimal solution for BTP

Brand Essence: Effervescent speed

Promote  
noncancer data

Receptive to  
*FENTORA* profile

Willing to try  
*FENTORA* in select  
BTP patients

Using *FENTORA*  
routinely in  
select BTP  
patients

Routine use of  
*FENTORA* to treat  
BTP in a broader  
population

*FENTORA* is  
viewed as the  
optimal therapy  
for BTP vs Oxy IR  
and other SAOs

Reducing use of  
ATC medications  
while maximizing  
benefits of  
*FENTORA*

2007 - 2008

2008 - 2009

# Three Year Strategy

What *FENTORA* Should Be: The optimal solution for BTP

Brand Essence: Effervescent speed

Promote  
superiority data

Receptive to  
*FENTORA* profile

Willing to try  
*FENTORA* in select  
BTP patients

Using *FENTORA*  
routinely in select  
BTP patients

Routine use of  
*FENTORA* to treat  
BTP in a broader  
population

*FENTORA* is  
viewed as the  
optimal therapy  
for BTP vs Oxy IR  
and other SAOs

Reducing use of  
ATC medications  
while maximizing  
benefits of  
*FENTORA*

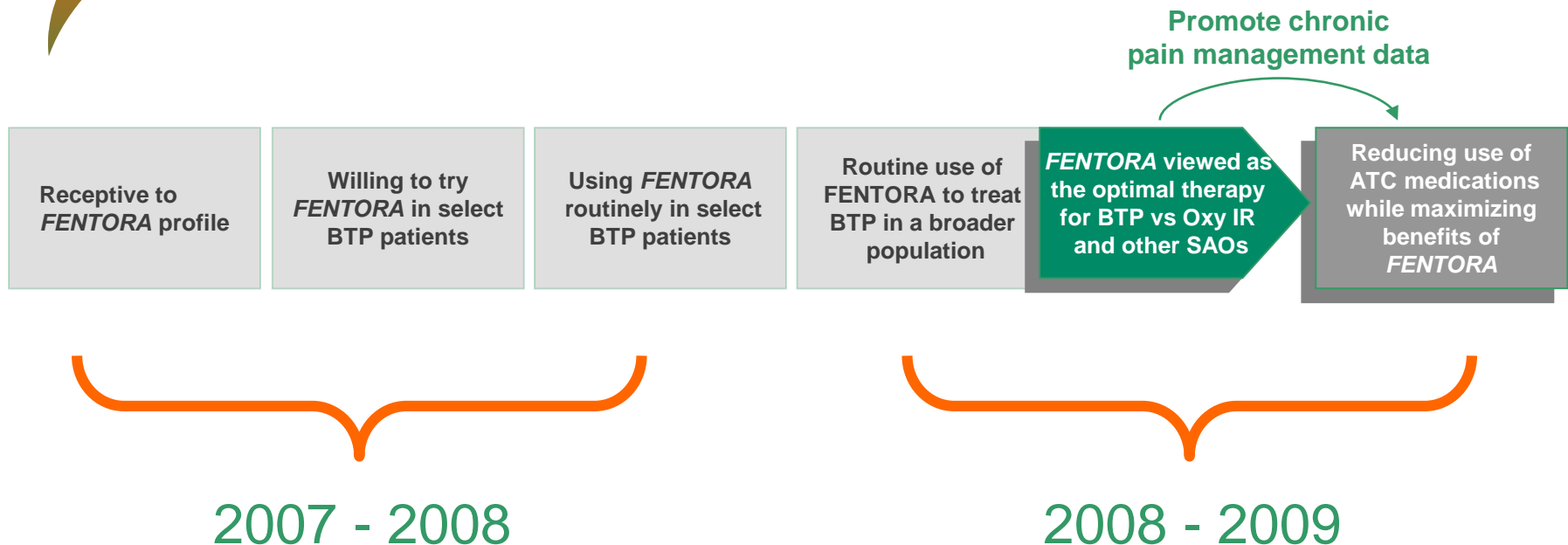
2007 - 2008

2008 - 2009

# Three Year Strategy

What *FENTORA* Should Be: The optimal solution for BTP

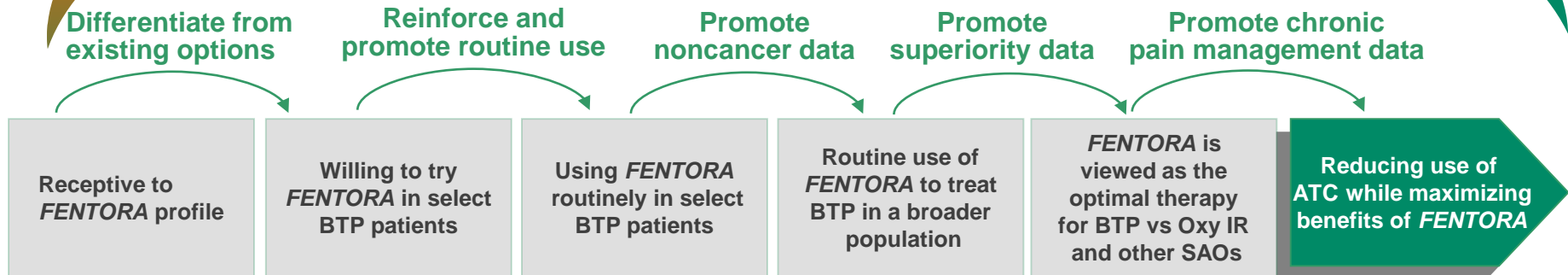
Brand Essence: Effervescent speed



# Three Year Strategy

What *FENTORA* Should Be: The optimal solution for BTP

Brand Essence: Effervescent speed



## *FENTORA* Positioning

*FENTORA* is the first and only fentanyl buccal tablet that utilizes an effervescence reaction to provide the most **rapid onset** of analgesia of any oral opioid resulting in improved patient functioning and activities of daily living

# Marketing Strategy

## 2007 Objectives, CSFs, Strategies

**FENTORA<sup>TM</sup>**  
*fentanyl buccal tablet* ®

# Objectives 2007

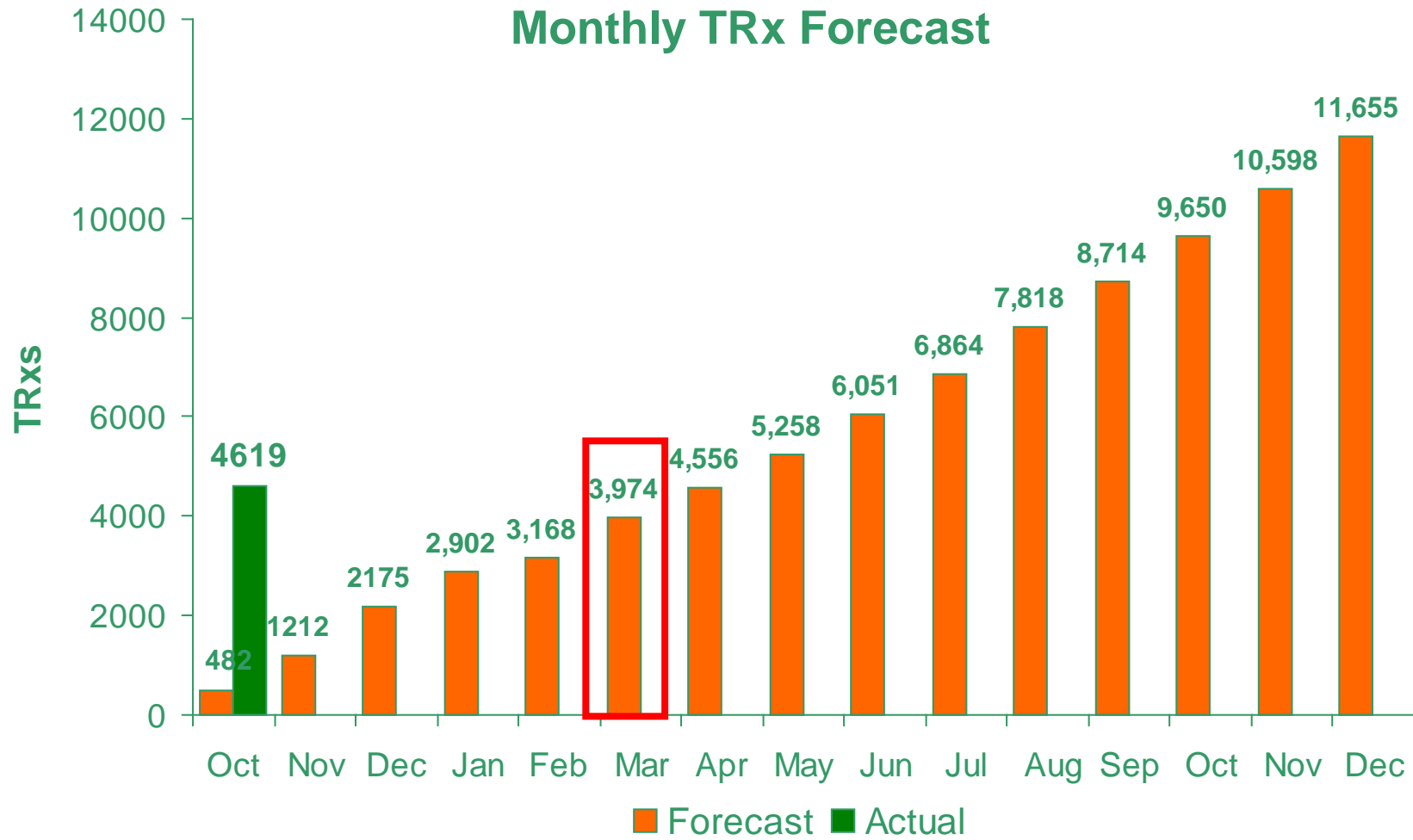
**\$139.5M Total Revenue**  
**81,207 TRxs**

## Assumptions

- TRx Share @ month 12 = 28% of ROO (fentanyl) Market
- FENTORA will grow from Actiq conversion & incremental market growth
- WAC/TRx = \$1,357 (2.5% annual price increase)

# TRx Objectives

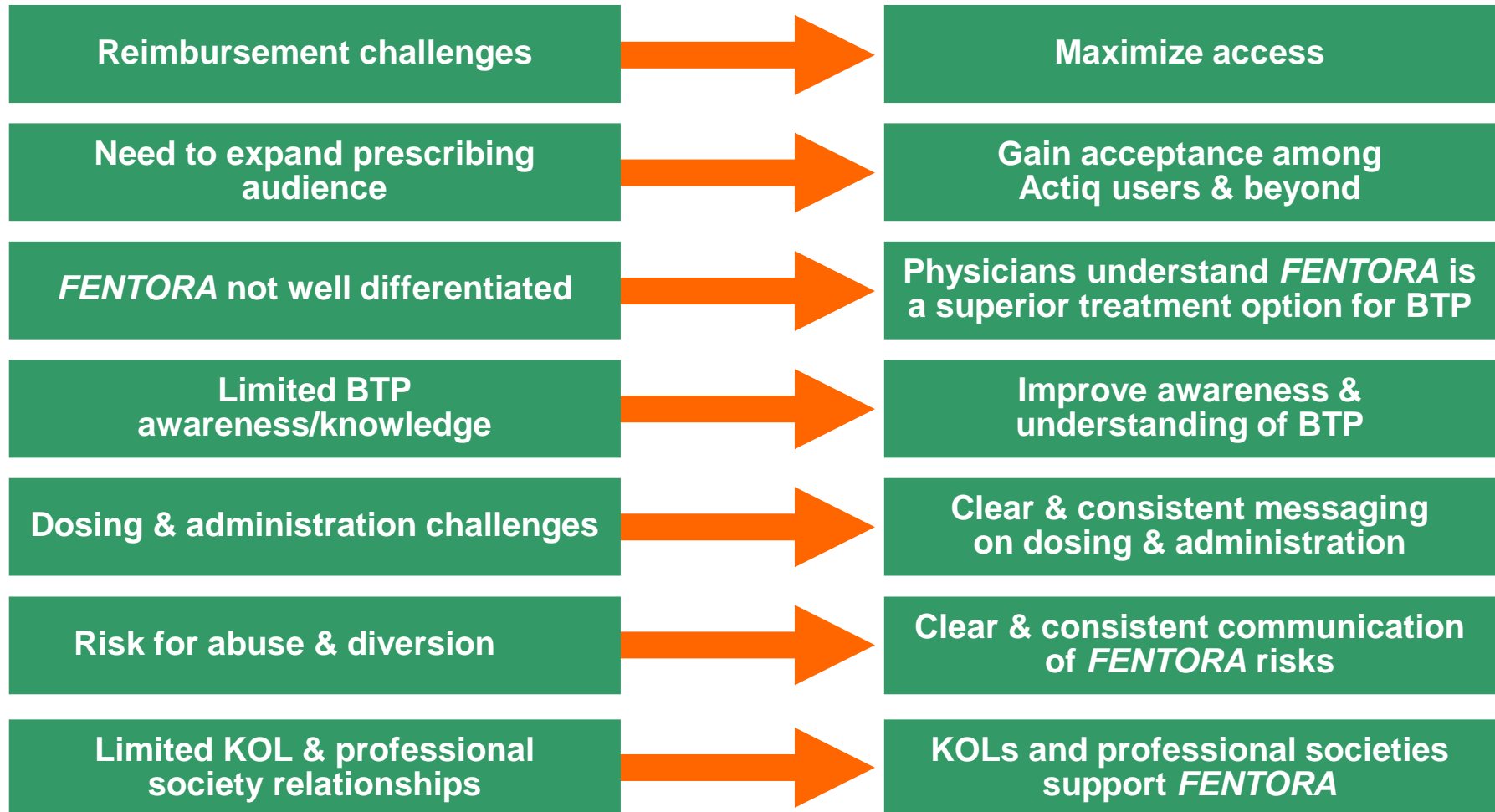
## 2006 - 2007



# Critical Success Factors

## Issues

## CSFs





# Key Strategies – FENTORA

## Issue

Third Party Payers manage costs by placing reimbursement limitations/restrictions on premium priced therapies

## Critical Success Factor

Physicians & patients have access to reasonable/favorable reimbursement for FENTORA

## Strategies

Manage and mitigate managed care barriers (cost, generic step-edit):

- Selectively contract with MCOs
- Educate MCOs regarding:
  - FENTORA value to health system
  - BTP:
    - Optimal assessment and treatment of BTP
    - Establish the Burden of Illness of BTP
    - Further develop ROO sub-class as an optimal treatment for BTP
  - Minimize risk of Abuse, Addiction, and Diversion
- Provide physician/patient assistance access programs

# Key Strategies – FENTORA

## Issue

Limited number of health care providers prescribe a ROO for BTP

## Critical Success Factor

Expand FENTORA prescribing audience with Actiq users and beyond

## Strategies

- Maximize core prescriber to set the stage for expanded use
- Expand use with high opioid prescribers and low Actiq users
- Explore broader audience, non-retail segment opportunities, as well as other potential channels

# Key Strategies – FENTORA

## Issue

FENTORA is not clearly differentiated from other BTP and non-BTP treatment options

## Critical Success Factor

Physicians understand FENTORA is a superior treatment option for BTP

## Strategies

- Create high level of awareness among target segments
- Educate physicians on the potential limitations of prescribing LAOs and SAOs to treat BTP
- Leverage new clinical data when available and appropriate
- Further develop ROO sub-class as an optimal treatment for BTP

# Key Strategies – FENTORA

## Issue

Physicians and patients have limited understanding about the appropriate diagnosis and treatment of BTP; a contributing factor is the communication disconnect between physicians and patients in regards to pain

## Critical Success Factor

BTP awareness and understanding of treatment options among physicians and patients

## Strategies

- Continue to establish BTP as a distinct clinical problem among opioid prescribing physicians
- Facilitate dialogue between physicians and patients to improve the proper diagnosis and treatment of BTP
- Support BTP educational initiatives

# Key Strategies – FENTORA

## Issue

Anticipated dosing and administration challenges for both physicians and patients

## Critical Success Factor

Physicians and patients understand the proper dosing and administration of FENTORA

## Strategies

Educate physicians and patients on

- How the delivery system is different from traditional oral administration
- Dosing, conversion and titration
- Package Handling & Administration

# Key Strategies – FENTORA

## Issue

Limited KOL and professional society relationships impact peer-to-peer knowledge and uptake of FENTORA

## Critical Success Factor

KOLs and societies support FENTORA as an effective treatment option for BTP

## Strategies

- Improve and expand KOL and society relationships
- Continue to consult KOLs to better inform Cephalon on the optimal design of FENTORA clinical studies, as well as the positioning of the brand

# Key Strategies – FENTORA

## Issue

Risk for abuse, addiction, and diversion

## Critical Success Factor

FENTORA risks are understood by health care professionals

## Strategies

- Educate HCPs on appropriate patient selection
- Educate patients about safe use of FENTORA and allay fears of opioids
- Continue to implement risk minimization tools
- Maximize SECURE outreach program initiatives

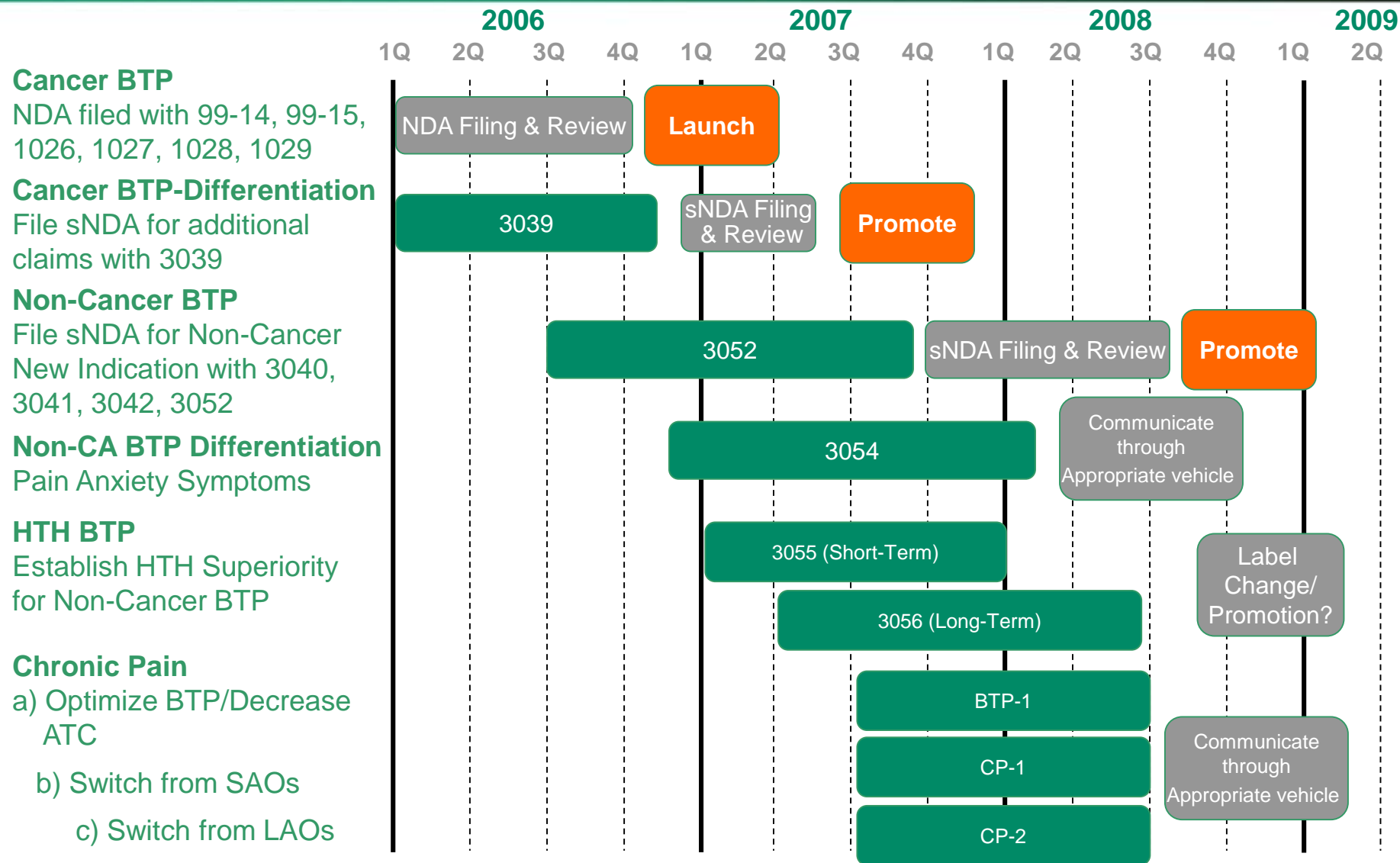
# What's going to get us there

## Enhancing the Product Profile: Clinical Development Plan

**FENTORA<sup>TM</sup>**  
*fentanyl buccal tablet* ®



# LCM Plan



Note – Promotion is based on positive clinical results

# *FENTORA* Clinical Update

***FENTORA***<sup>TM</sup>  
*fentanyl buccal tablet* ®

# New BTP Efficacy Data in Patients with Cancer

**FENTORA<sup>TM</sup>**  
*fentanyl buccal tablet* ®

Study 3039  
Efficacy, Safety, and Tolerability  
Study in Patients with Cancer and  
Breakthrough Pain

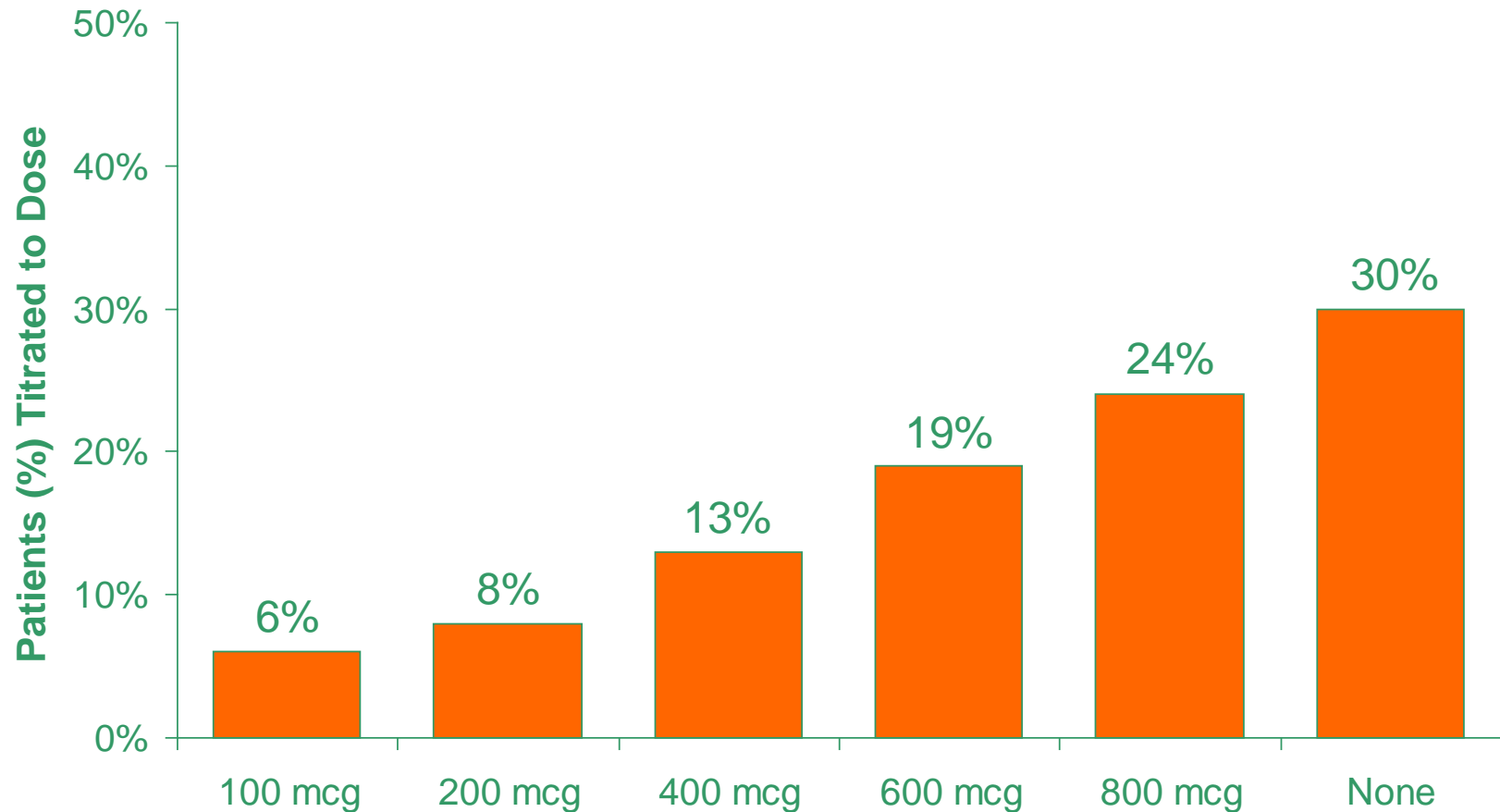
**FENTORA<sup>TM</sup>**  
*fentanyl buccal tablet @*

# Efficacy Measures with Each Episode

- Pain Intensity- (0= no pain to 10= worst pain)
  - Completed prior to dosing and at 5, 10, 15, 30, 45, 60, 90, 120 min post dosing
- Pain Relief- (0= none to 4= complete)
  - Completed at 5, 10, 15, 30, 45, 60, 90, 120 min post dosing
- Time to meaningful pain relief
- Use of Rescue Medication
- Global Medication Performance Assessment (0= poor to 4= excellent)
  - 60 and 120 min post dose

Case 1:17-md-02804-DAP Doc #: 2557-18 Filed: 08/30/19 94 of 150. PageID #: 411901

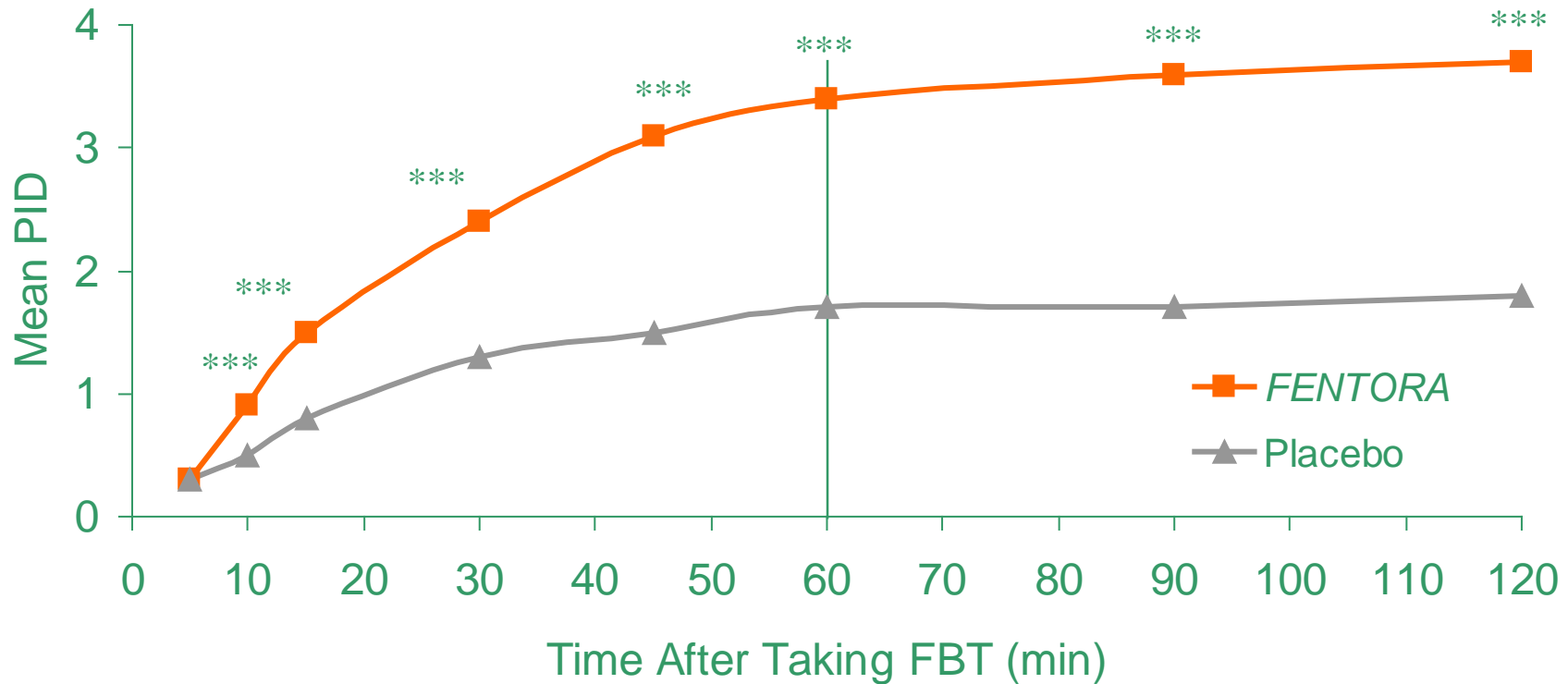
# Successful Dose of *FENTORA* Following Titration



Successful dose = The dose strength that provided adequate analgesia for 2 consecutive episodes of BTP without unacceptable adverse events.

# Mean Pain Intensity Differences (PID) Over Time

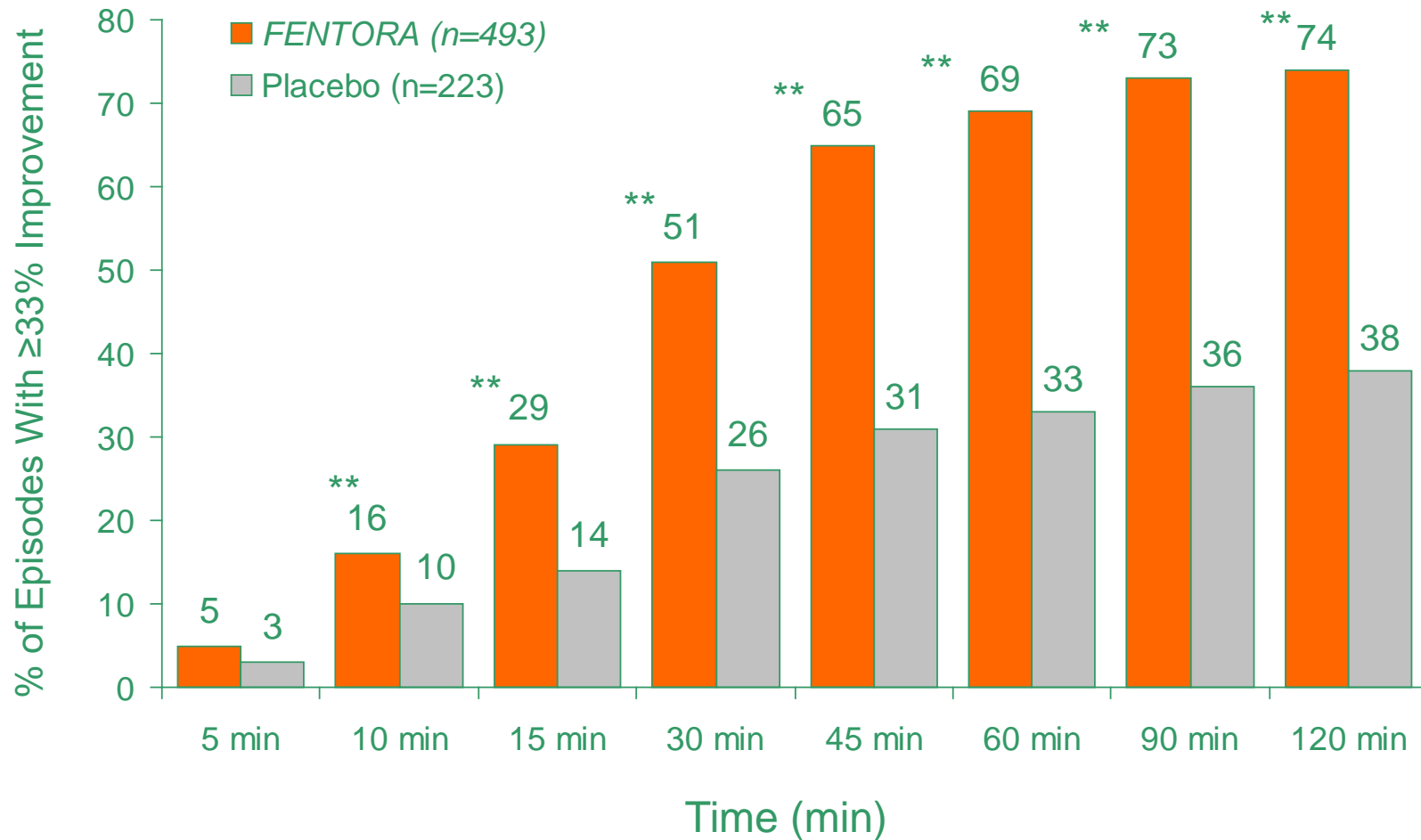
SPID<sub>60</sub>: *FENTORA*  $9.8 \pm 0.26$  vs Placebo  $5.0 \pm 0.38$   $p < 0.0001$



\*\*\*  $P < 0.0001$

# Clinically Significant Change in Pain Intensity ( $\geq 33\%$ Reduction)

Case: 1:17-md-02804-DAP Doc #: 2557-18 Filed: 08/30/19 96 of 150. PageID #: 411903



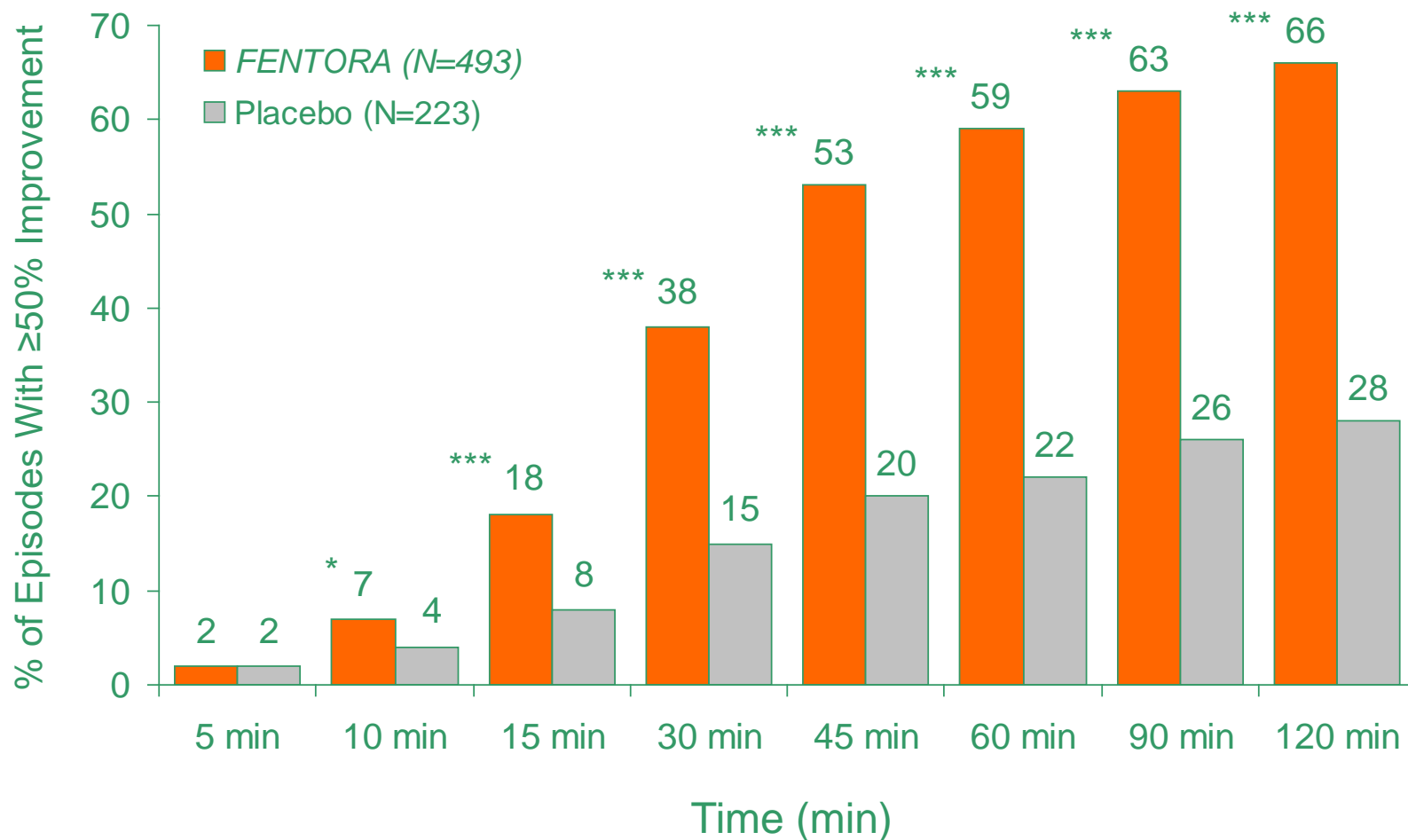
\*\*  $P < 0.01$

Study 3039



# Clinically Significant Change in Pain Intensity (>50% Reduction)

Case: 1:17-md-02804-DAP Doc #: 2557-18 Filed: 08/30/19 97 of 150. PageID #: 411904



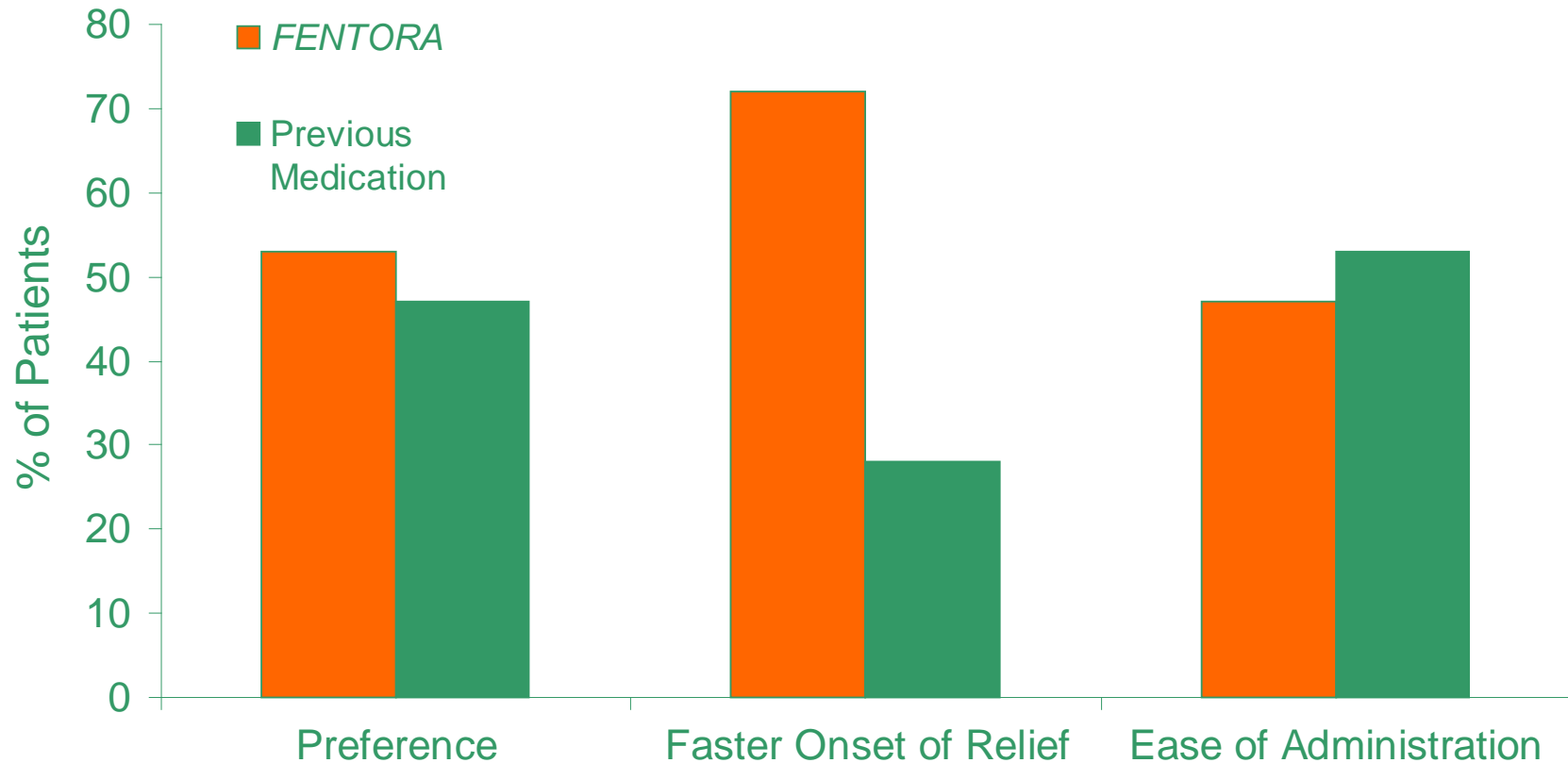
\*  $P < 0.05$

\*\*\*  $P < 0.0001$

Study 3039

Case: 1:17-md-02804-DAP Doc #: 2557-18 Filed: 08/30/19 98 of 150 PageID #: 411905

# Patients Prefer *FENTORA* to Previously Used Medication



# Study 3039 Conclusions

- *FENTORA* was significantly superior to placebo on all measures of efficacy
- Efficacy observed as early as early as 10 minutes after taking *FENTORA* and maintained through 120 minutes
- First study in which clinically relevant responses separate at 10 min time point
- Episodes treated with placebo were over ~3x as likely to require rescue medication as those treated with *FENTORA*
- Well tolerated with AEs being typical of opioids; frequency less than that seen in 099-14

# Non-Cancer Program

***FENTORA***<sup>TM</sup>  
*fentanyl buccal tablet* ®

# Noncancer BTP Clinical Trials

- **3040:** Open-label, 18-month study in chronic pain patients with BTP
- **3041:** Double-blind, placebo-controlled, short-term efficacy study in neuropathic pain patients
- **3042:** Double-blind, placebo-controlled, short-term efficacy study in low-back pain patients
- **3052:** Double-blind, placebo-controlled, 12-week efficacy study in chronic pain patients
- **3054:** Open-Label, 4-week study in chronic pain patients  
Evaluating the Impact of *FENTORA* on Pain Associated Anxiety

# Status of Noncancer Studies

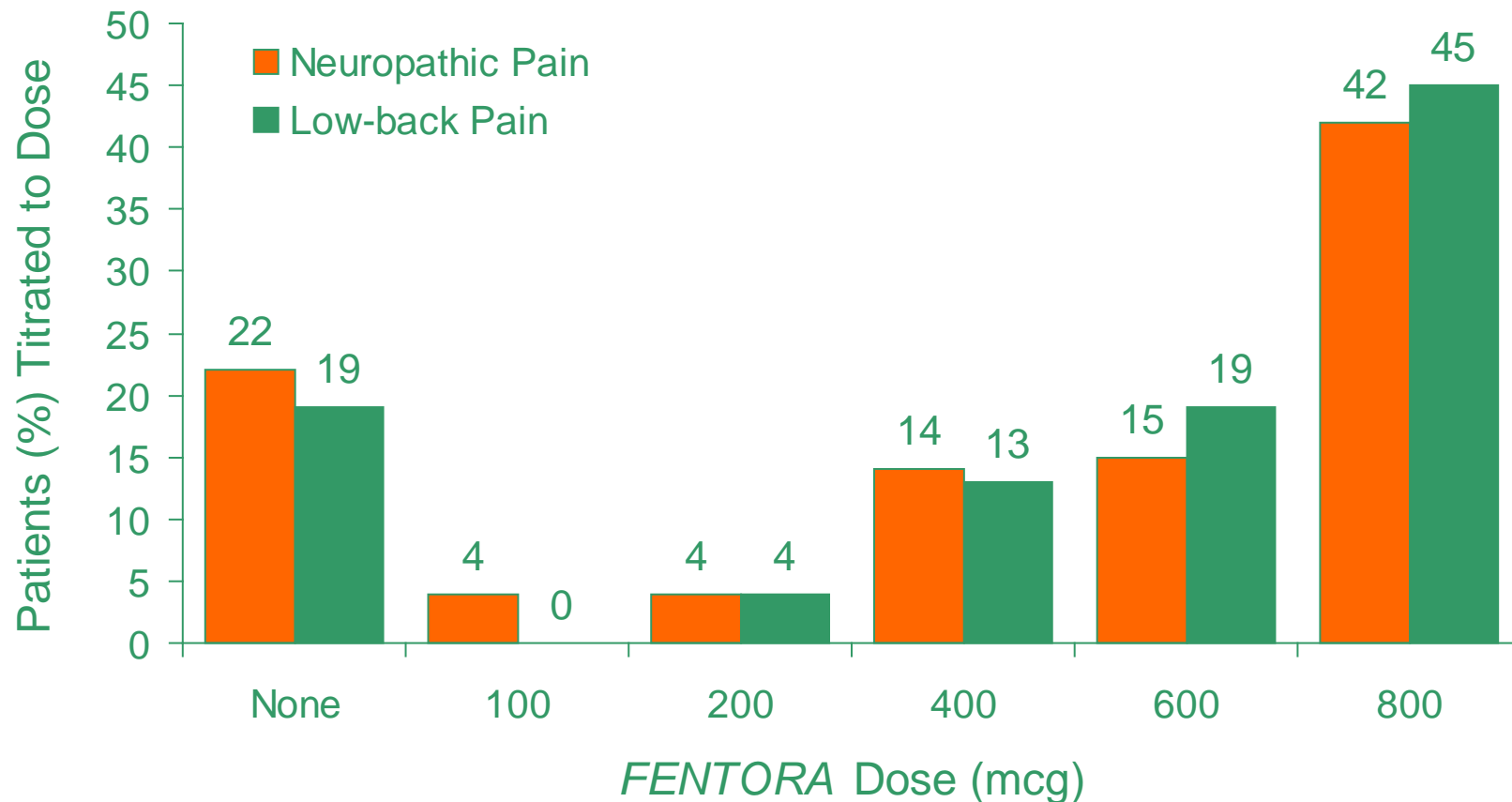
- **Supportive efficacy studies**
  - **3041**: completed
  - **3042**: completed
- **3040**
  - >800 patients exposed
  - >180 patients exposed for 1 year
- **3052**
  - Pivotal study
  - “Agreement” with US Food and Drug Administration on study design
  - 91/120 patients enrolled
- **3054**
  - First patient screened November 27, 2006
- **Supplemental New Drug Application**
  - To be submitted 4Q2007

# Effects of *FENTORA* in Opioid-tolerant Patients With Non-cancer-related BTP

## Results from Studies 3041 and 3042

***FENTORA***<sup>TM</sup>  
*fentanyl buccal tablet* ®

# Successful Dose Following Titration

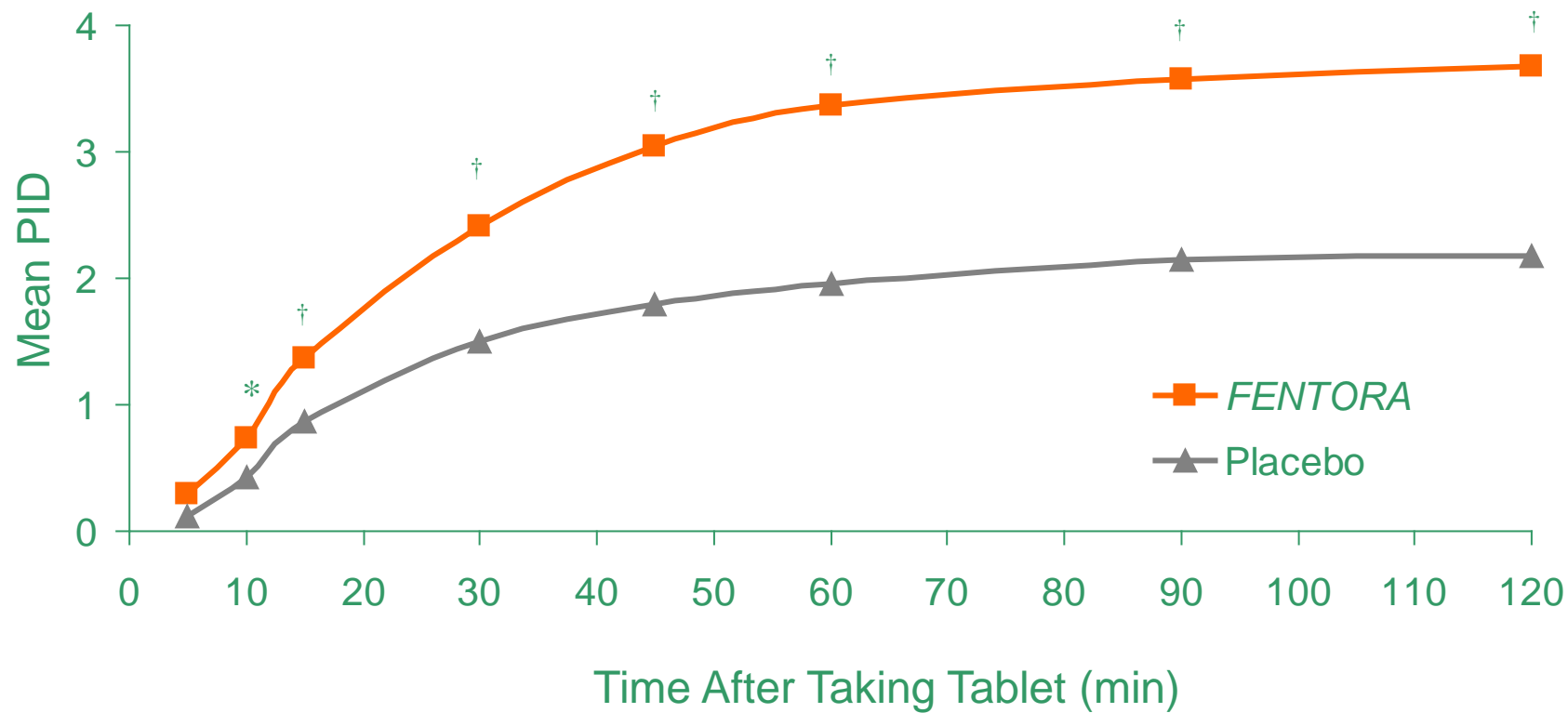


Successful dose = the dose strength that provided adequate analgesia for two thirds of episodes of BTP without unacceptable AEs



# Mean PIDs Over Time

## Study 3041: Neuropathic Pain

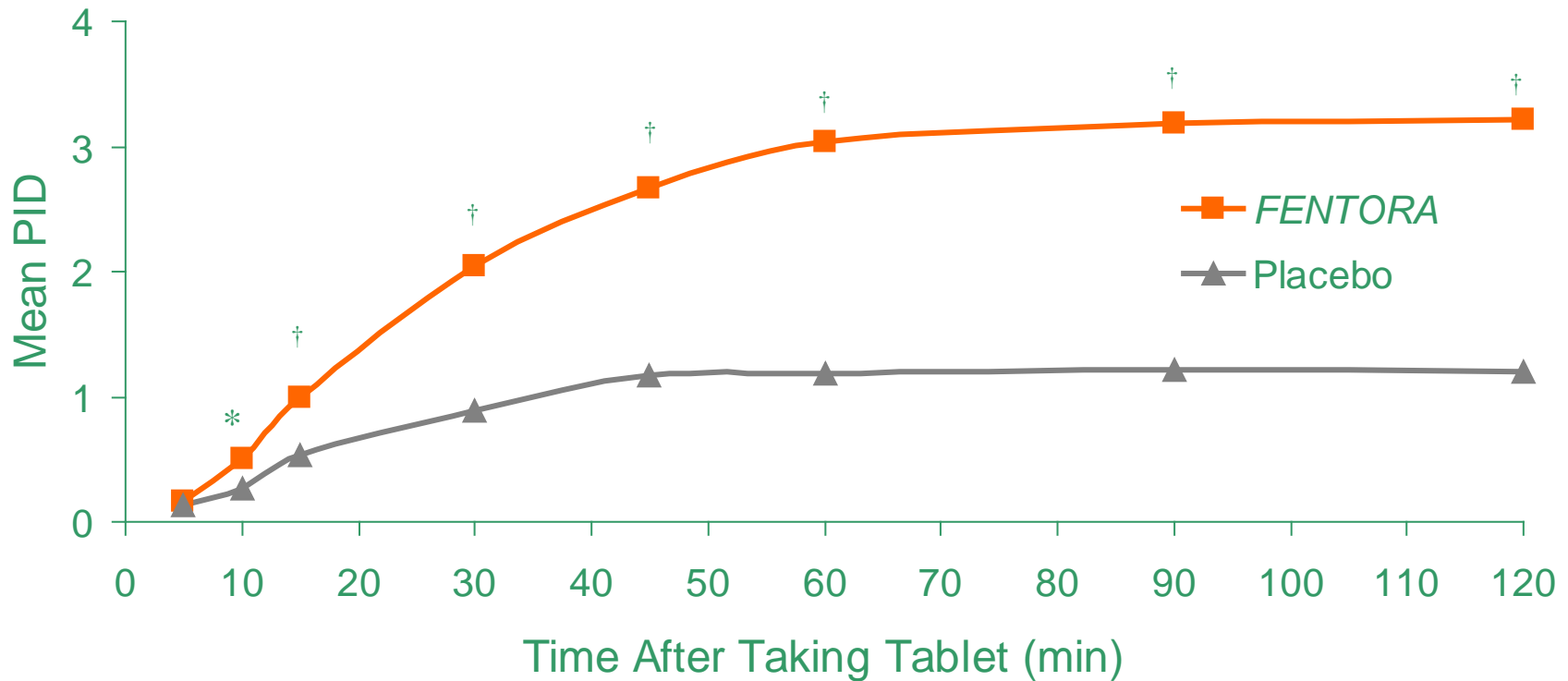


\* $P=.0436$

† $P<.01$

# Mean PIDs Over Time (cont'd)

## Study 3042: Low-back Pain

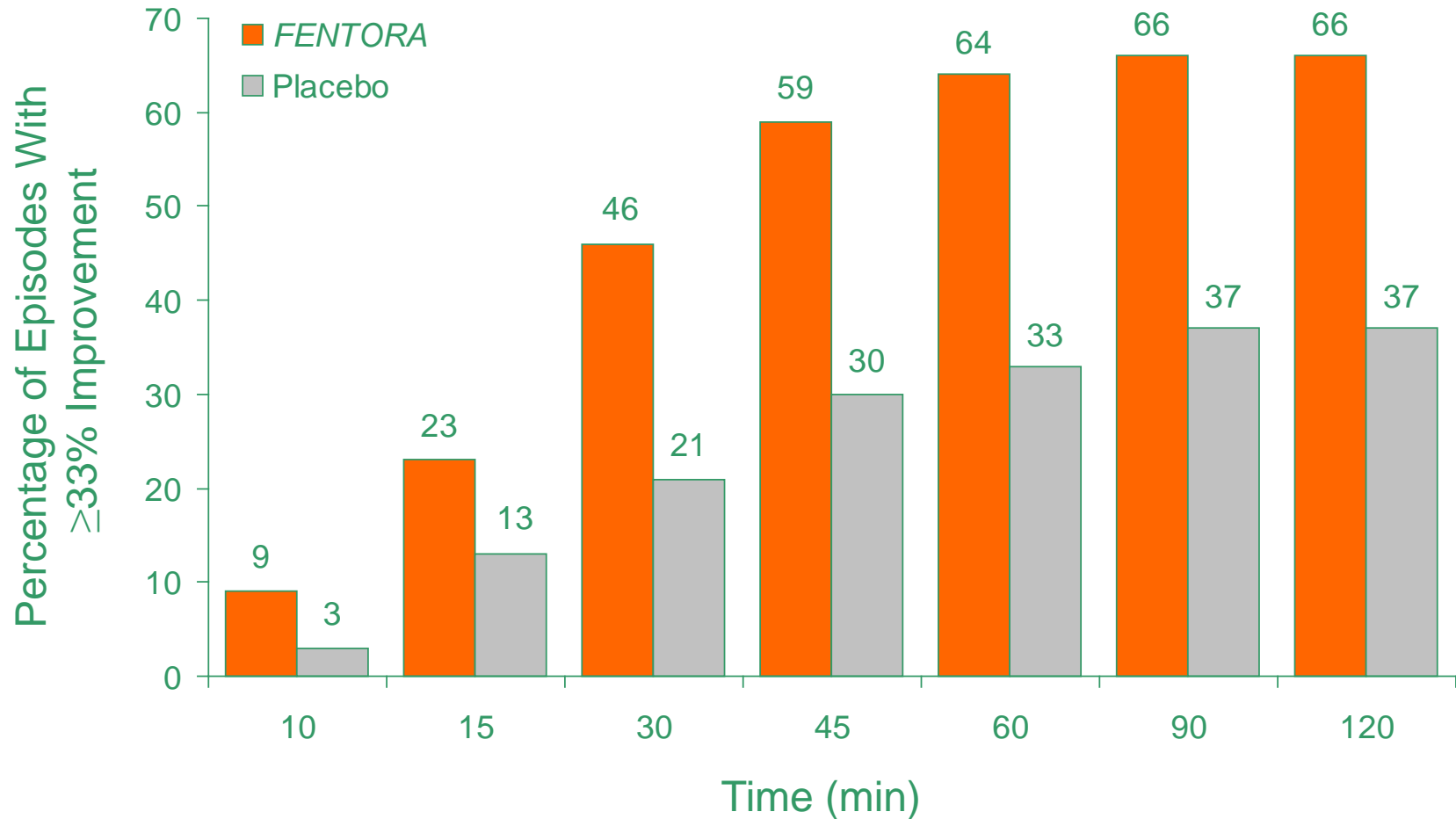


\* $P=.0039$

† $P<.001$

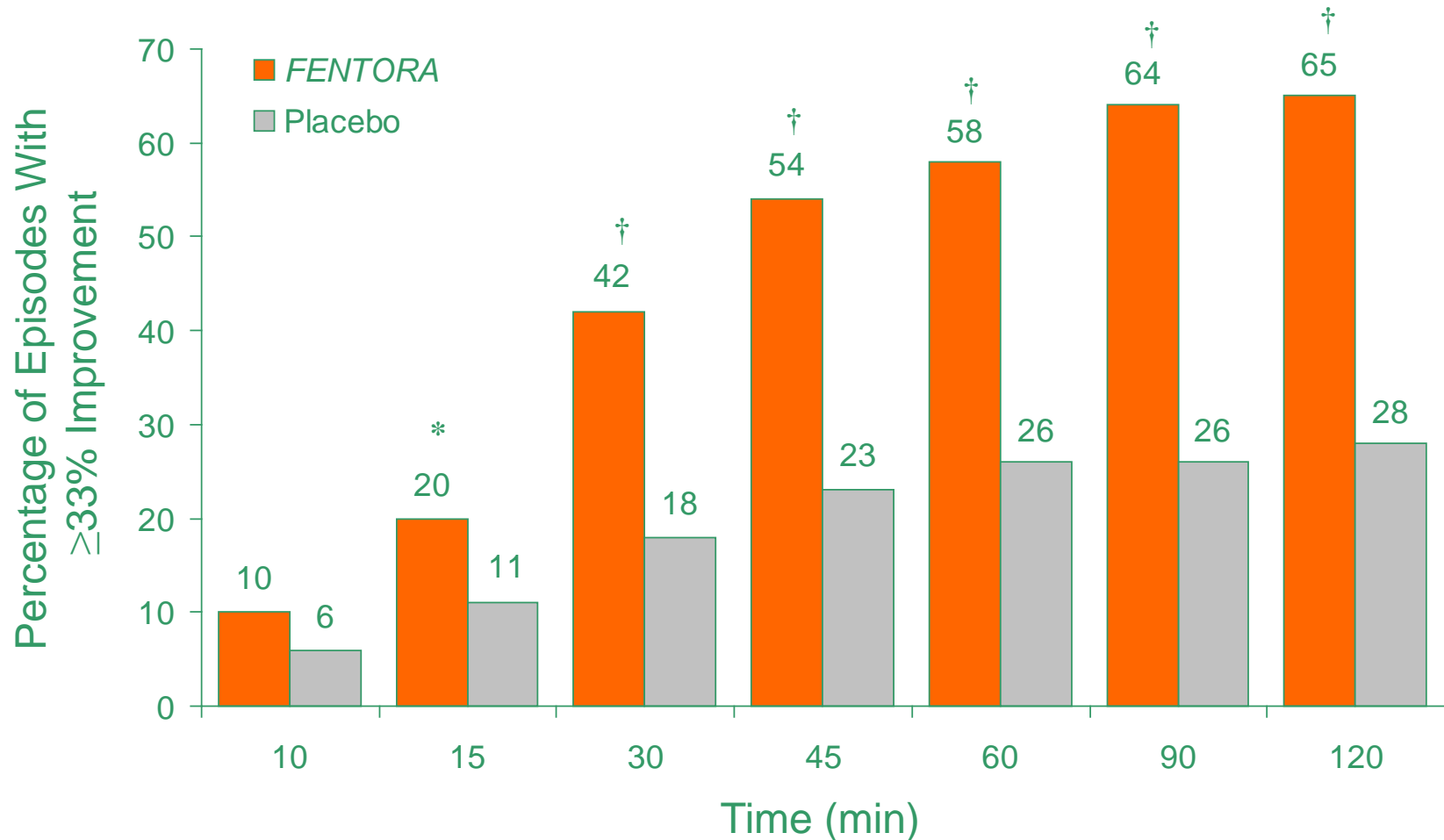
# Clinically Significant ( $\geq 33\%$ ) Change in Pain Intensity

## Study 3041: Neuropathic Pain



# Clinically Significant ( $\geq 33\%$ ) Change in Pain Intensity (cont'd)

## Study 3042: Low-back Pain

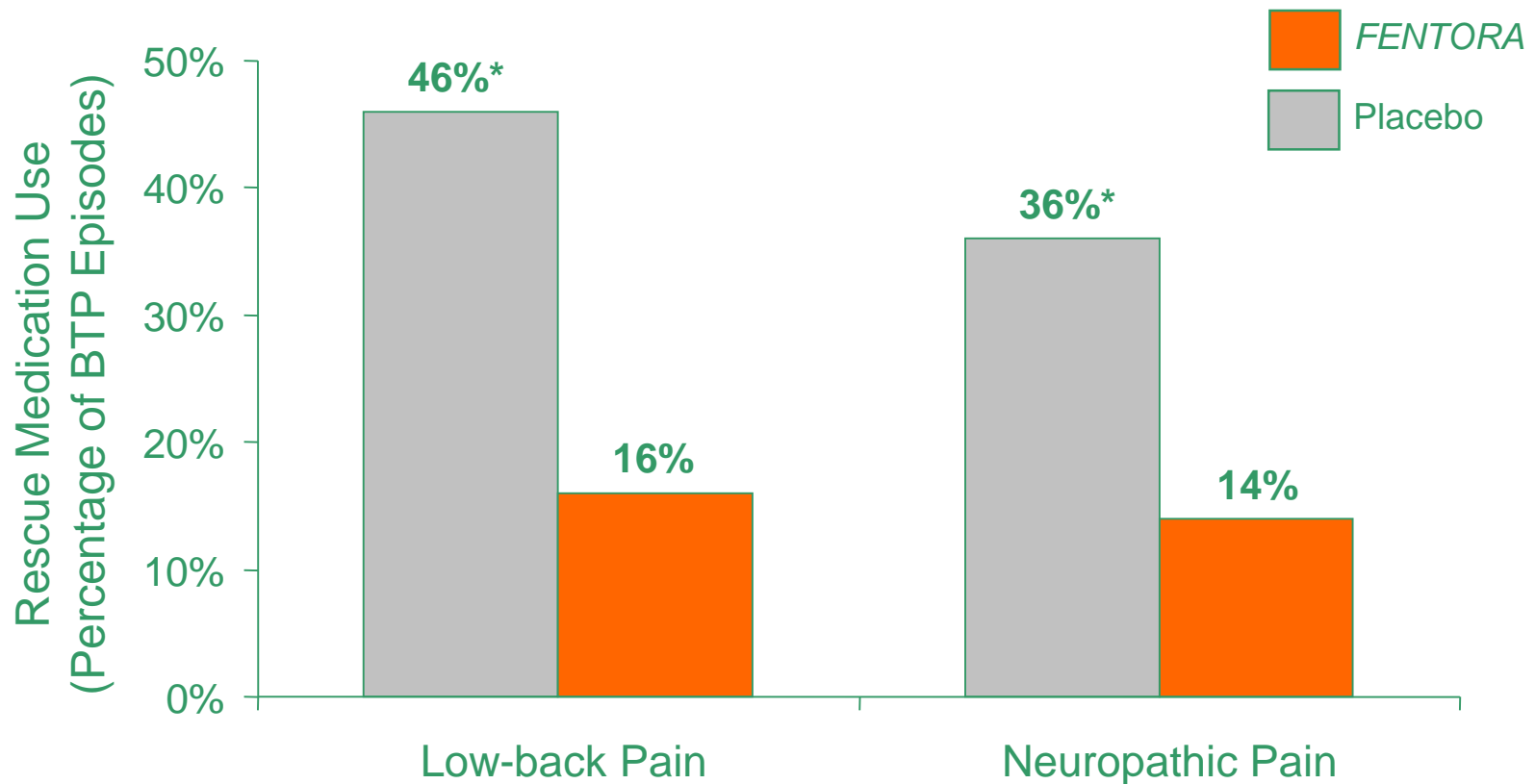


\* $P=.008$

† $P<.001$

Case: 1:17-md-02804-DAP Doc #: 2557-18 Filed: 08/30/19 109 of 150 PageID #: 411916

# Rescue Medication Use in Chronic Neuropathic Pain and Chronic Low-back Pain Studies



\* $P \leq .05$

# Conclusions From Chronic Neuropathic Pain and Chronic Low-back Pain Studies

Case: 1:17-md-02804-DAP Doc #: 2557-18 Filed: 08/30/19 110 of 150. PageID #: 411917

- >80% of patients in both studies found a successful *FENTORA* dose in the range of 100 mcg to 800 mcg
- Patient populations had significant comorbidities
- Efficacy first observed as early as 10 minutes after taking *FENTORA* and maintained through 120 minutes in both studies
- Clinically significant pain relief greater with *FENTORA* compared with placebo as early as 15 minutes
- Episodes treated with placebo were more than 4x as likely to require rescue medication as those treated with *FENTORA*
- *FENTORA* was well tolerated and AEs typical of those seen with opioids

# Study 3040

## Open-label Non-Cancer Pain

### Interim Results

**FENTORA<sup>TM</sup>**  
*fentanyl buccal tablet* ®

# Global Medication Performance Assessment

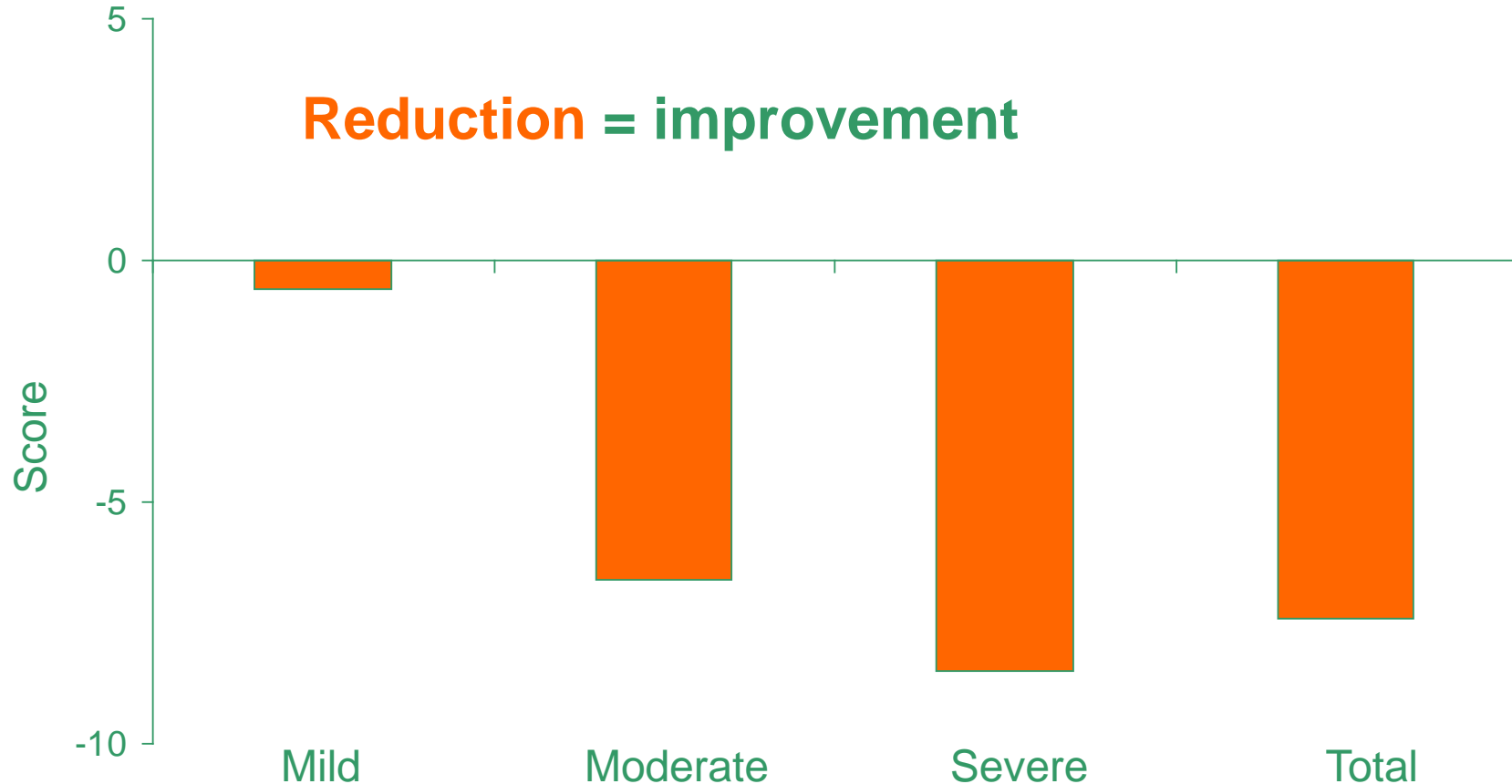


Data represent last available assessment

Study 3040



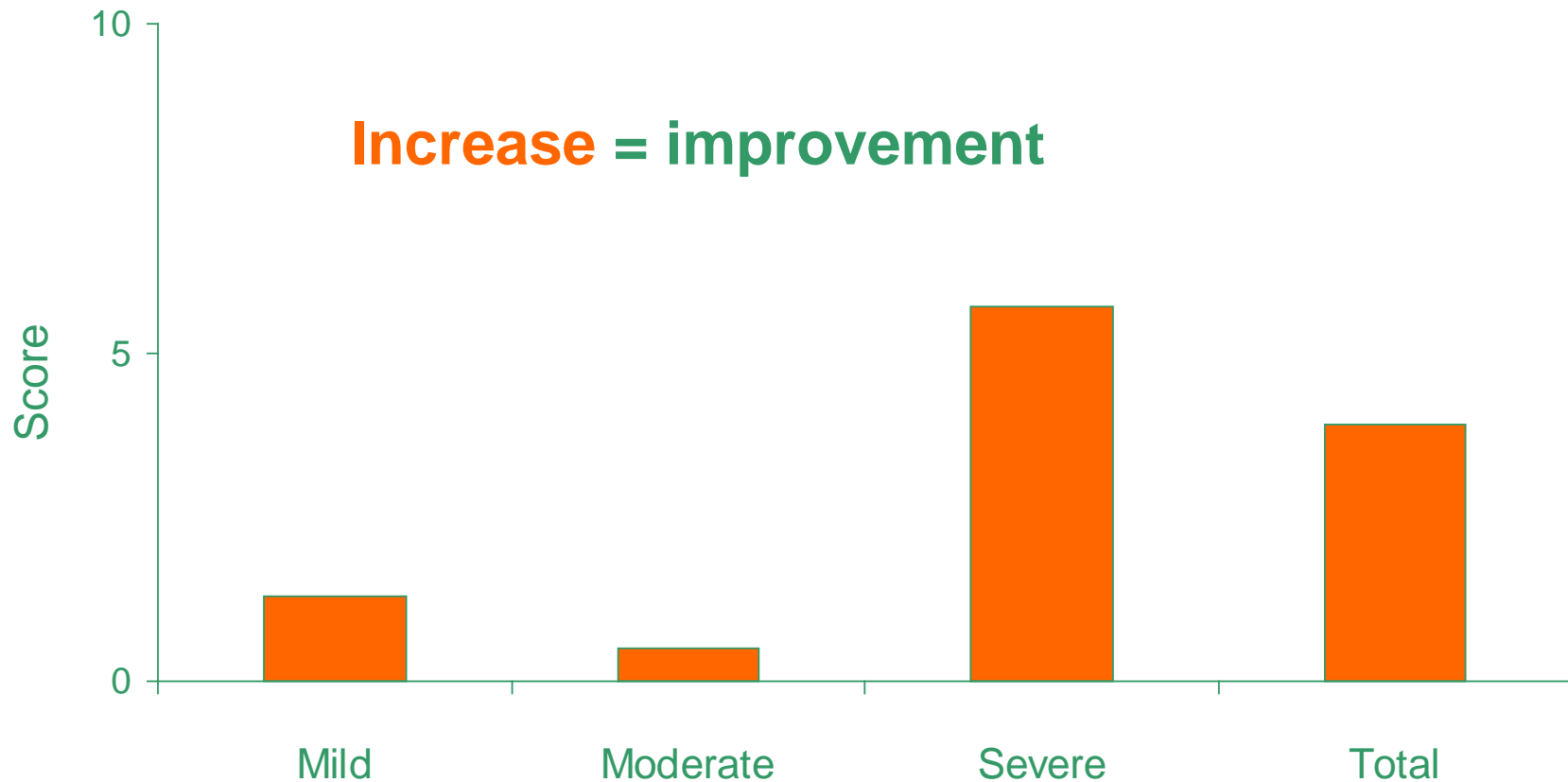
# POMS Total Mood Disturbance: Change From Baseline (3 Months)



POMS = profile of mood states

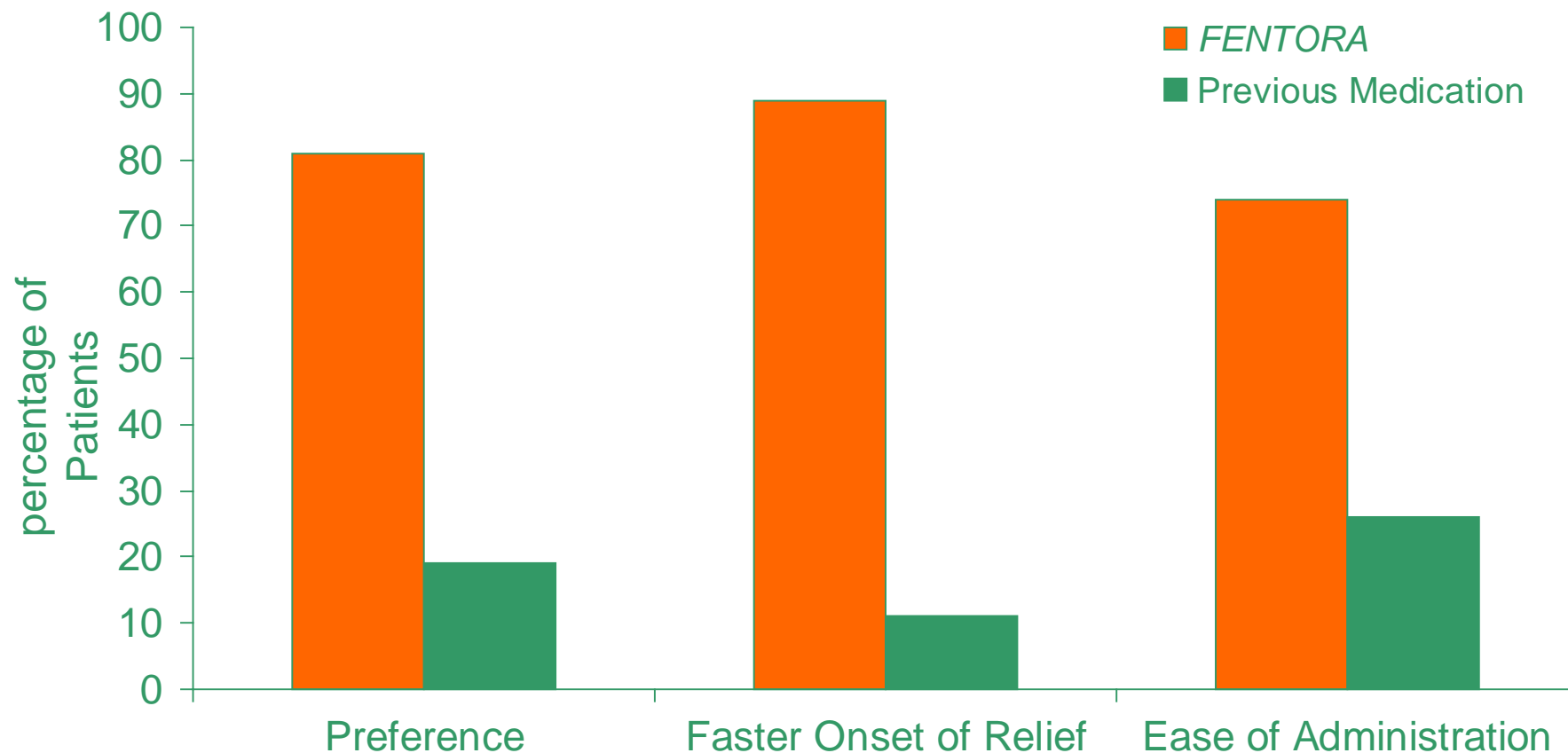
Study 3040

# SF-36 Physical Functioning: Change From Baseline (3 Months)



Case: 1:17-md-02804-DAP Doc #: 2557-18 Filed: 08/30/19 115 of 150. PageID #: 411922

# Patients Prefer *FENTORA* to Previously Used Medication



Assessed after 1 month of maintenance

Study 3040

# Summary of Interim Data

- Patients reflective of intended population
  - Back pain was the most prevalent condition
  - Patients had a high number of comorbid conditions
- *FENTORA* was well tolerated
  - 88% of patients found a successful dose
  - AEs were those commonly associated with opioid use
- Patients overwhelmingly reported a preference for *FENTORA* versus their previous BTP medication

# New Studies for 2007

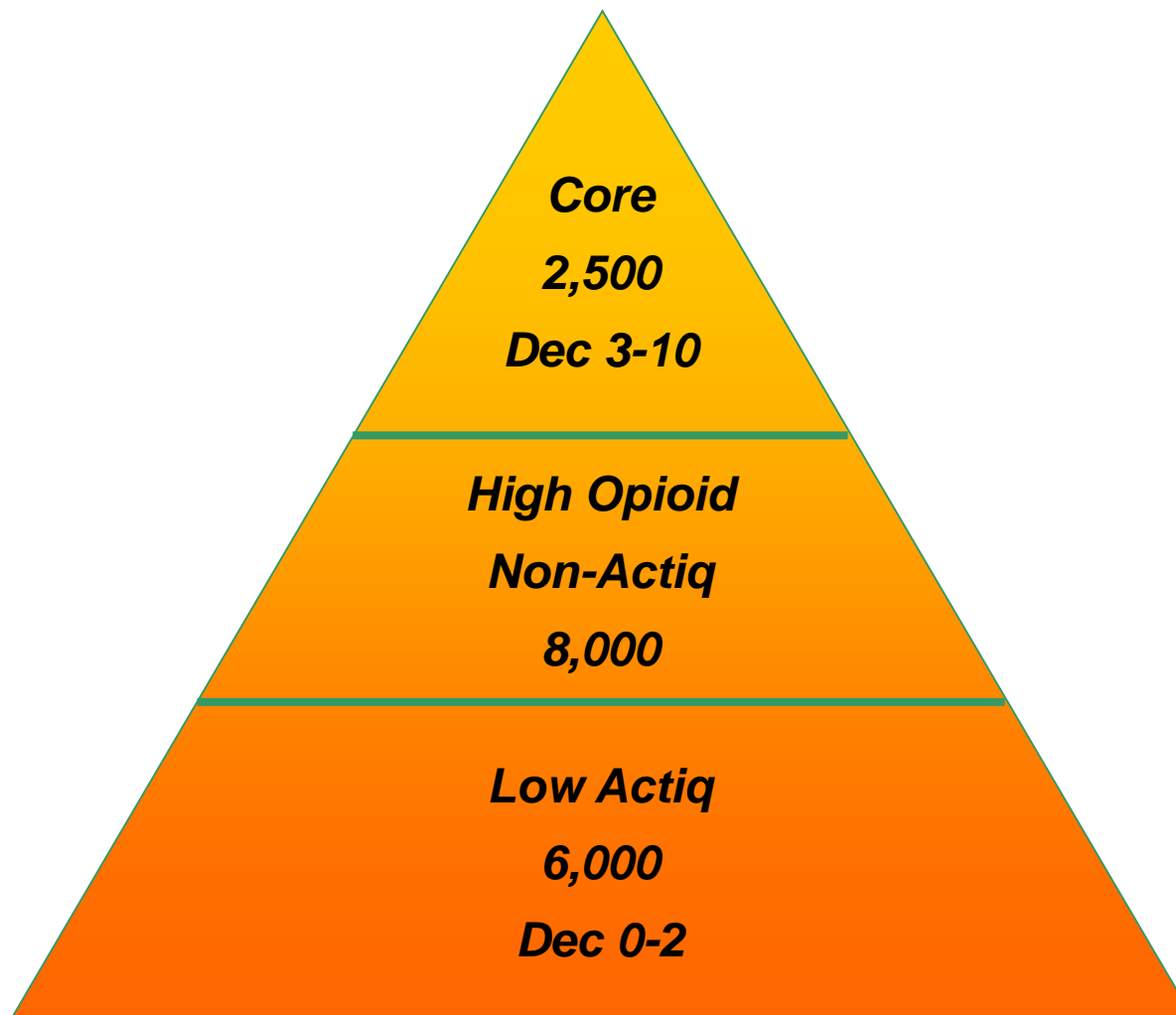
- PK
  - Sublingual vs Buccal Delivery – Nov 2006
  - Evaluation of 1000 and 1200 mcg doses – 1Q2007
- Clinical Studies
  - 2 Head-to-Head studies against oxycodone IR
    - 3055 – March 2007
    - 3056 – July 2007
  - 2 Relative potency studies
    - 1046 – *FENTORA* vs IV Morphine January 2007
    - ## – *FENTORA* vs Oxycodone IR 4Q 2007

# What's going to get us there

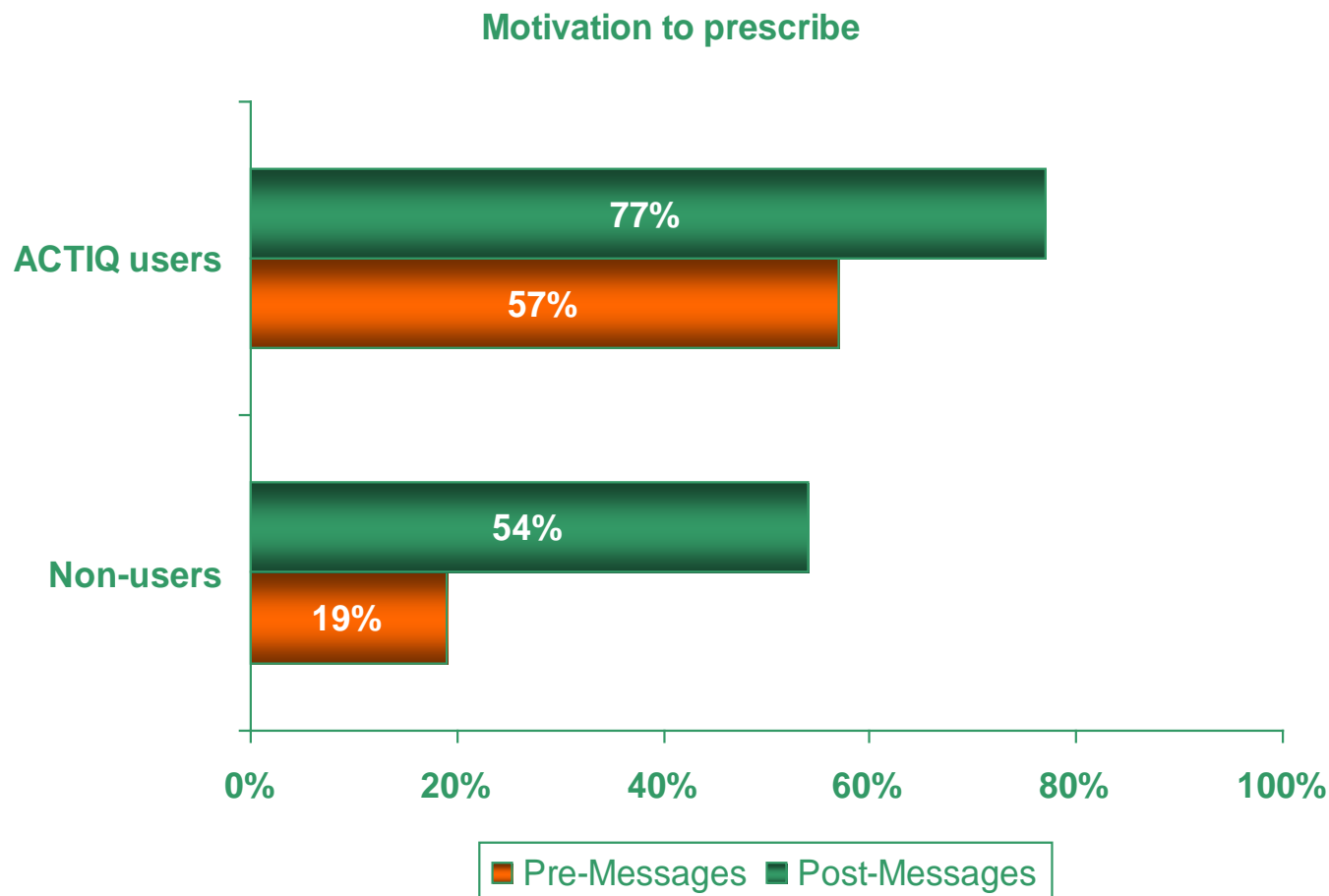
## Effective Targeting & Tactics

**FENTORA<sup>TM</sup>**  
*fentanyl buccal tablet* ®

# Targeting



# Rxers Reaction to Messages

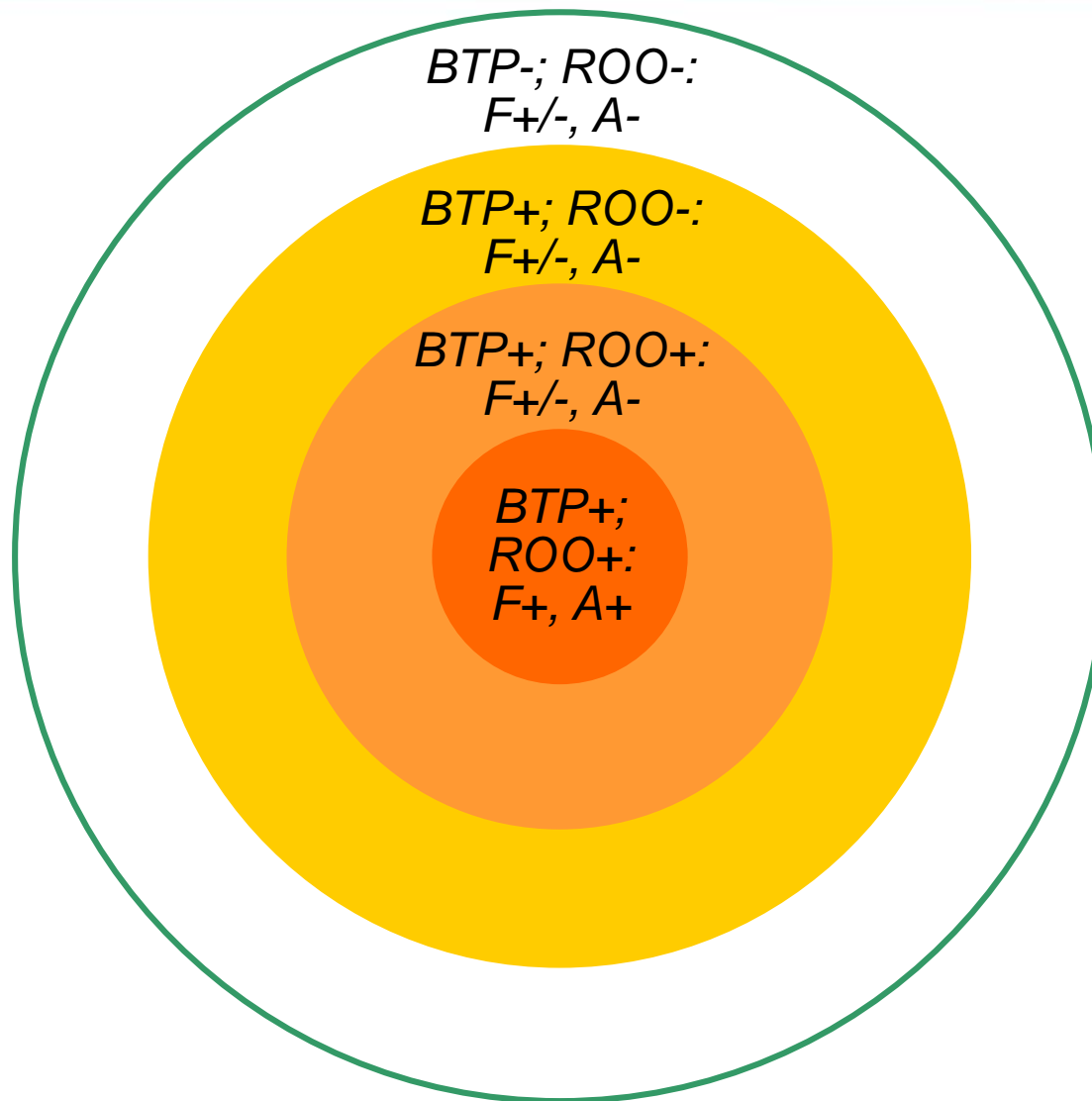


\* To what degree does this new information motivate you to prescribe FENTORA over other short-acting opioid (SAO) medications for breakthrough pain (1-7 scale)?

Source: Gfk V2 Q2 06 N = 77 (users) N = 52 (non-users) 121



# Targeting



# Tactical Plan

**FENTORA<sup>TM</sup>**  
*fentanyl buccal tablet* ®

# CSF #1: Physicians & patients have access to reasonable/favorable reimbursement for *FENTORA*

## STRATEGY

- Selectively contract with MCOs
- Educate MCOs regarding:
  - *FENTORA* value to health system
  - BTP:
    - Optimal assessment and treatment of BTP
    - Establish the Burden of Illness of BTP
    - Further develop ROO sub-class as an optimal treatment for BTP
  - Minimize risk of Abuse, Addiction, and Diversion
- Provide physician/patient assistance access programs

## TACTICS

- AMCP Dossier
- NAM Slide Kit
- Formulary Kit
- Reprints
- BTP Collateral Material
  - Direct Mail, Journal Ads, targeted media
- ESP Tool Kit & Collateral
- AMCP Convention Presence
- Reimbursement Kit / Hotline
- Debit Card Pilot Program
- In-Office Reimbursement Training

# CSF #2: Expand FENTORA prescribing audience beyond Actiq users

## STRATEGY

- Maximize core prescribers to set the stage for expanded use
- Expand use with high opioid prescribers and low Actiq users
- Explore non-retail segments opportunities, as well as other potential channels

## TACTICS

- NSM Workshops
- Field driven promotional programs
  - CSPs – \$6M
  - Vouchers – 75/rep 1st half, 50/rep 2nd half
  - Sales collateral materials (w/ 3039)
    - Actiq users material
    - Animation, case study series
  - Hospital program – grand rounds
  - Reprints
- Marketing driven promotional programs
  - Direct mail, targeted media, journal ads
  - E-detail
  - Website
  - Convention presence

## CSF #3: Physicians understand *FENTORA* is a superior treatment option for BTP

### STRATEGY

- Create high level of awareness among target segments
- Educate physicians on the potential limitations of prescribing LAOs and SAOs to treat BTP
- Leverage new clinical data when available and appropriate
- Further develop ROO sub-class as an optimal treatment for BTP

### TACTICS

- Appropriate dissemination of clinical data
- Branded collateral material
- CSPs
- Case Studies Program
- *FENTORA* animation
- PR outreach to KOLs, societies, advocacy groups, & pain centers of excellence
- Government affairs outreach to USP
- SECURE educational initiatives

## **CSF #4: BTP awareness and understanding of treatment options among physicians and patients**

### **STRATEGY**

- Continue to establish BTP as a distinct clinical problem among opioid prescribing physicians
- Facilitate dialogue between physicians and patients to improve the proper diagnosis and treatment of BTP
- Support BTP educational initiatives

### **TACTICS**

- BTP campaign
  - Journal ad & targeted media
  - DA Convention Booth
  - BTP website
  - Direct Mail
  - PR initiatives (outreach, etc)
- ISS Support (e.g. Knox Todd, MD)
- Appropriate support of 3rd party educators
- In-office patient material

# CSF #5: Physicians and patients understand the proper dosing and administration of *FENTORA*

## STRATEGY

- Educate physicians and patients on
  - How the delivery system is different from traditional oral administration
  - Dosing and titration
  - Package Handling & Administration

## TACTICS

- Administration poster
- Wallet card
- Administration script for Prof Services
- Pain diary
- Flip chart
- Patient starter kit
- Catalina newsletter
- E-detail
- Pod cast
- Blackberry download (in booth promotion)
- Case Studies

## CSF #6: *FENTORA* risks are understood by health care professionals

### STRATEGY

- Educate HCPs on appropriate patient selection
- Educate patients about safe use of *FENTORA* and allay fears of opioids
- Continue to implement risk minimization tools
- Maximize SECURE outreach program initiatives

### TACTICS

- Branded collateral materials
- Lunch & Learns
- AAD CSPs
- SECURE educational initiatives
- ESP initiatives
- Media outreach training (issues mgt)



# CSF #7: KOLs and societies support FENTORA as an effective treatment option for BTP

## STRATEGY

- Improve and expand select KOL and society relationships
- Continue to consult KOLs to develop clinical & commercial plans

## TACTICS

- Implement KOL Plan, e.g. roundtables, congress interaction, one-on-ones, HOVs
- Speaker Training / CSPs
- Media outreach training
- Society outreach initiatives, e.g. educational programs
- Implement Pain Centers of Excellence Program
- Ad Boards
- Consultant Meetings

# 2007 Promotional Budget

Category	Spend	Share of Total Spend
Market Research	\$1,750,000	6%
Consultants	\$400,000	1%
Journal Reprints	\$200,000	1%
Conventions	\$1,600,000	6%
Advertising/Promotional Materials	\$8,900,000	32%
Sample Coupons	\$6,000,000	21%
Public Relations	\$600,000	2%
Field Driven Speaker Programs (CSPs)	\$6,000,000	21%
Medical Education	\$2,500,000	9%
Corporate Contributions	\$50,000	0%
<b>TOTAL SPEND</b>	<b>\$28,000,000</b>	<b>100%</b>

# Tactical Plan

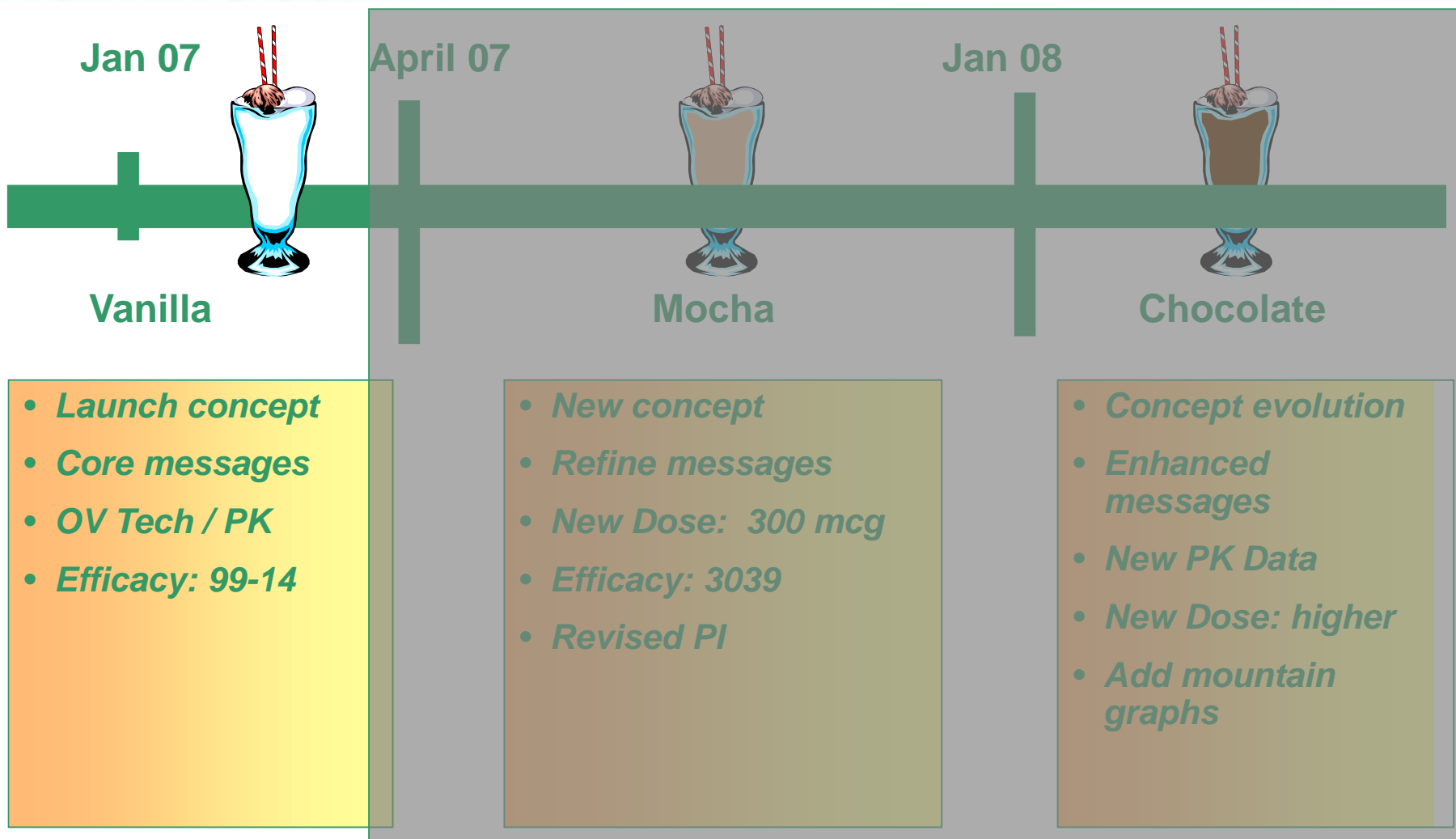
## ***FENTORA*** Campaign Evolution

***FENTORA***<sup>TM</sup>  
*fentanyl buccal tablet* ®

# Campaign



# Campaign Evolution



# Current Campaign

## New *FENTORA*—relief for breakthrough pain in opioid tolerant patients with cancer

- Onset of pain relief within 15 minutes in some patients<sup>\*1</sup>
- Duration of pain relief up to 60 minutes (last time point measured)<sup>1</sup>
- OraVescent® drug delivery technology may optimize delivery of fentanyl across the buccal mucosa<sup>1</sup>
- Fentanyl is readily absorbed, achieving an absolute bioavailability of 65%<sup>1</sup>
- Convenient, discreet, sugar-free tablet

**New**  
**FENTORA**  
fentanyl buccal tablet @

<sup>\*</sup>For patients with unrelied pain, redosing may occur 30 minutes after the start of administration with *FENTORA* and the same dosage strength should be used.

Serious adverse events associated with all opioids are respiratory depression (potentially leading to apnea or respiratory arrest), circulatory depression, hypotension, and shock. All patients should be followed for symptoms of respiratory depression.

The most commonly observed events seen with *FENTORA* are typical of opioid side effects. Opioid side effects should be expected and managed accordingly. In clinical trials of *FENTORA* the most common (≥10%) adverse events observed were nausea, vomiting, application site abnormalities, fatigue, anemia, dizziness, constipation, edema, asthenia, dehydration, and headache. Most side effects were mild to moderate in severity. No attempt was made to correct for concomitant use of around-the-clock opioids or cancer-related symptoms.

PHYSICIANS AND OTHER HEALTHCARE PROVIDERS MUST BECOME FAMILIAR WITH THE IMPORTANT WARNINGS IN THIS LABEL.

*FENTORA* contains fentanyl, an opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics. *FENTORA* can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing *FENTORA* in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse or diversion. Schedule II opioid substances which include morphine, oxycodone, hydromorphone, oxycodone, and methadone have the highest potential for abuse and risk of fatal overdose due to respiratory depression.

*FENTORA* is indicated for the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking at least 60 mg of oral morphine/day, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.

Because life-threatening respiratory depression can occur at any dose in opioid non-tolerant patients, *FENTORA* is contraindicated in the management of acute or postoperative pain. This product is not indicated for use in opioid non-tolerant patients.

Patients and their caregivers must be instructed that *FENTORA* contains a medicine in an amount which can be fatal to a child. Patients and their caregivers must be instructed to keep all tablets out of the reach of children. (See Information for Patients and Their Caregivers for disposal instructions.)

Due to the higher bioavailability of fentanyl in *FENTORA*, when converting patients from other oral fentanyl products, including oral transmucosal fentanyl citrate (OTC and Actiq®), to *FENTORA*, do not substitute *FENTORA* on a mcg per mcg basis. Adjust doses as appropriate. (See DOSAGE AND ADMINISTRATION.)

*FENTORA* is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

For more information about *FENTORA*, please call Cephalon Professional Services and Medical Information at 1-800-896-5855 or visit [www.FENTORA.com](http://www.FENTORA.com)

Please see boxed warning and brief summary of prescribing information on adjacent page.

Reference: 1. *FENTORA* (package insert). Frazer, Pa: Cephalon, Inc.; 2006.



deliver more?

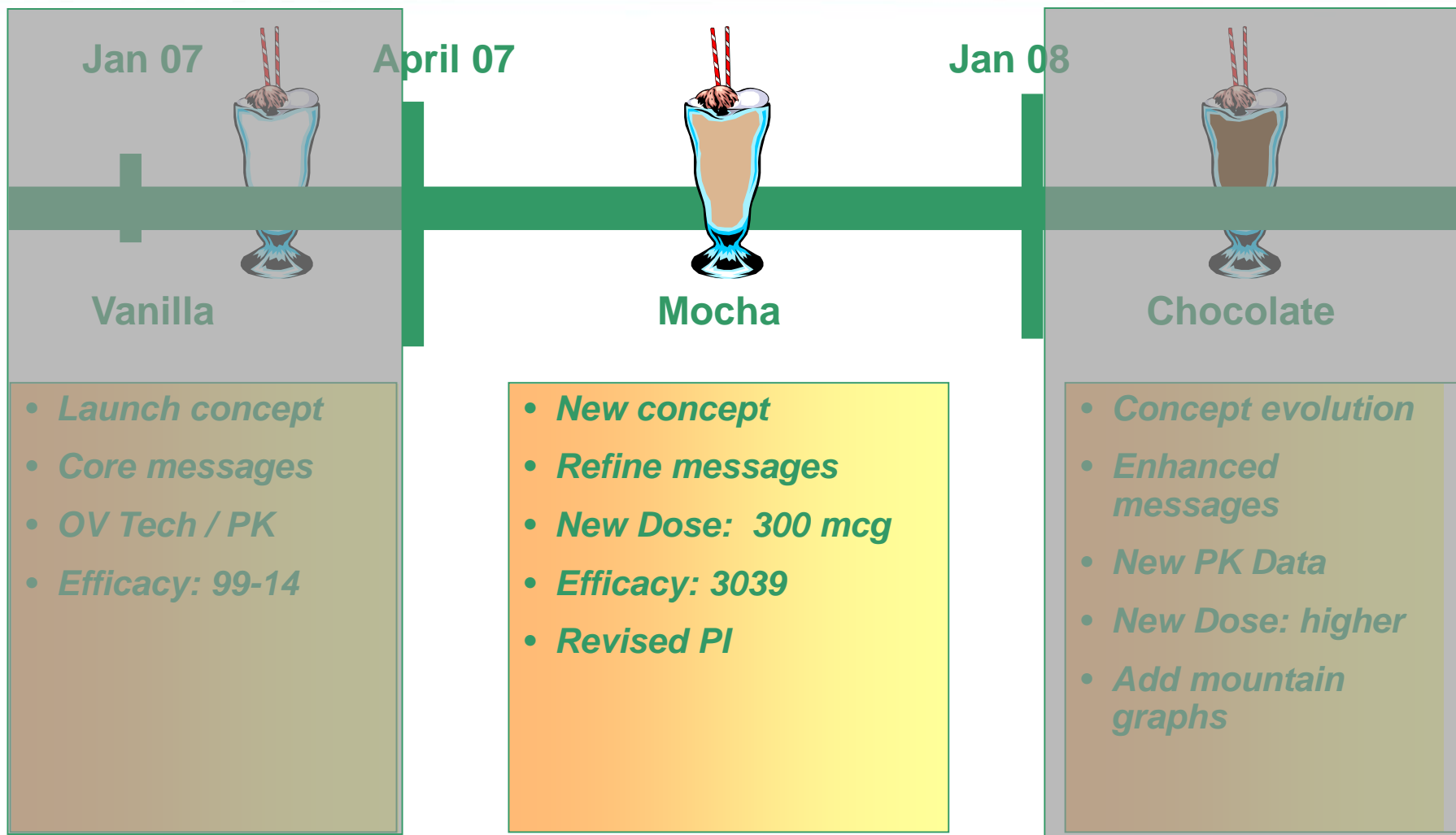
©2006 Cephalon, Inc. All rights reserved. FENT042 Oct 2006 Printed in USA.

## New *FENTORA*—relief for breakthrough pain in opioid tolerant patients with cancer

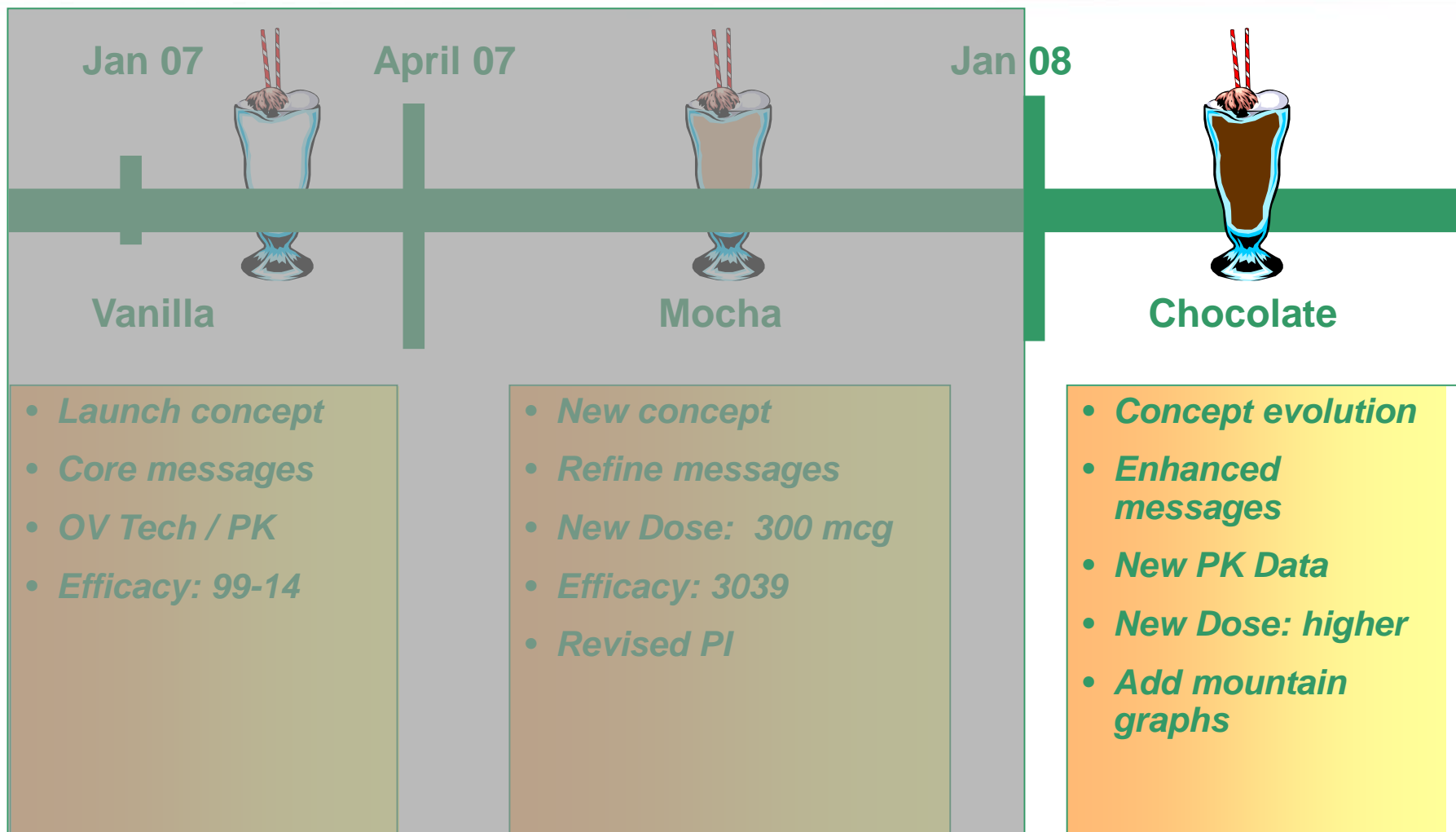
- Onset of pain relief within 15 minutes in some patients<sup>\*1</sup>
- Duration of pain relief up to 60 minutes (last time point measured)<sup>1</sup>
- OraVescent® drug delivery technology may optimize delivery of fentanyl across the buccal mucosa<sup>1</sup>
- Fentanyl is readily absorbed, achieving an absolute bioavailability of 65%<sup>1</sup>
- Convenient, discreet, sugar-free tablet

**FE**  
**fer**

# Campaign Evolution

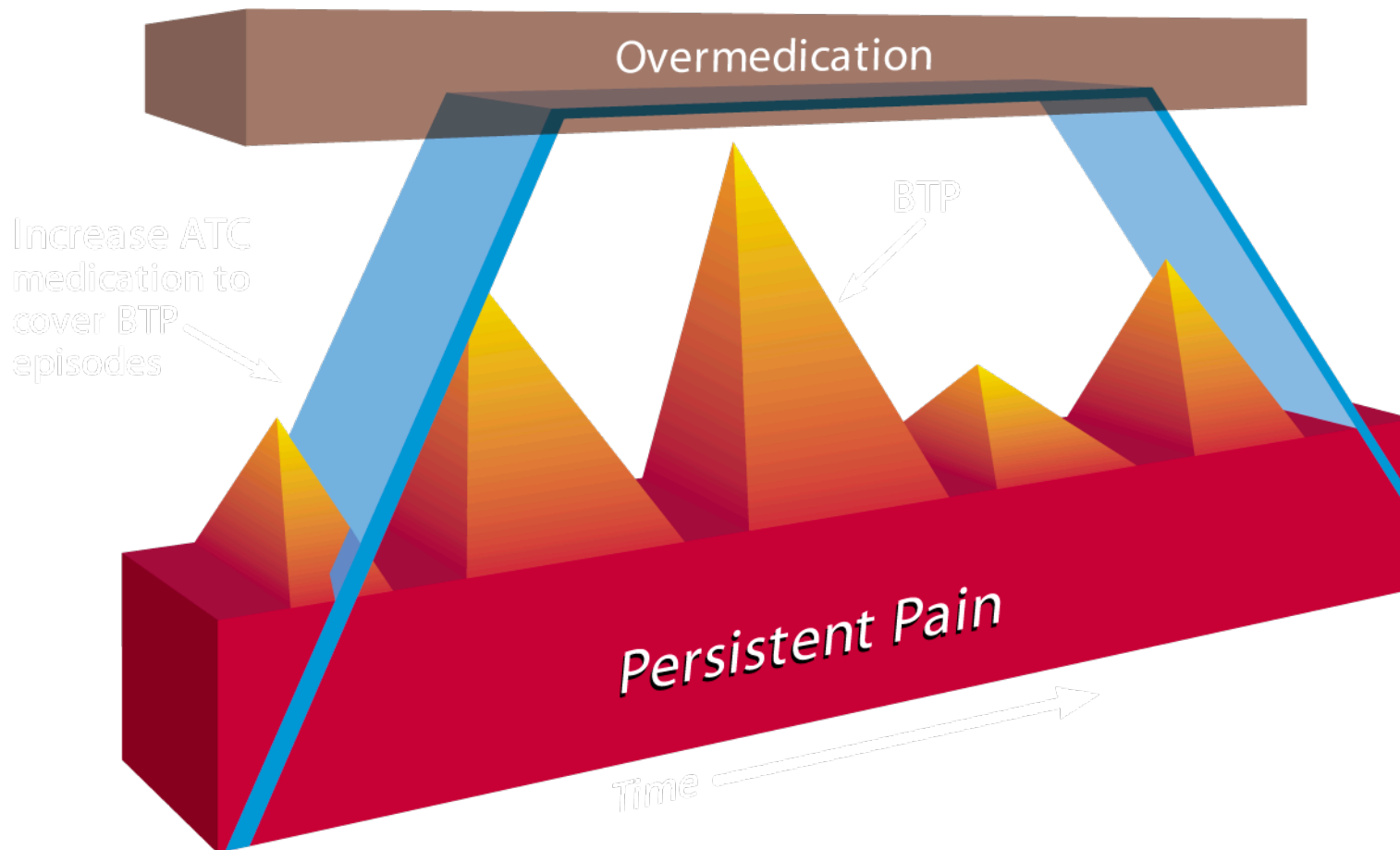


# Campaign Evolution

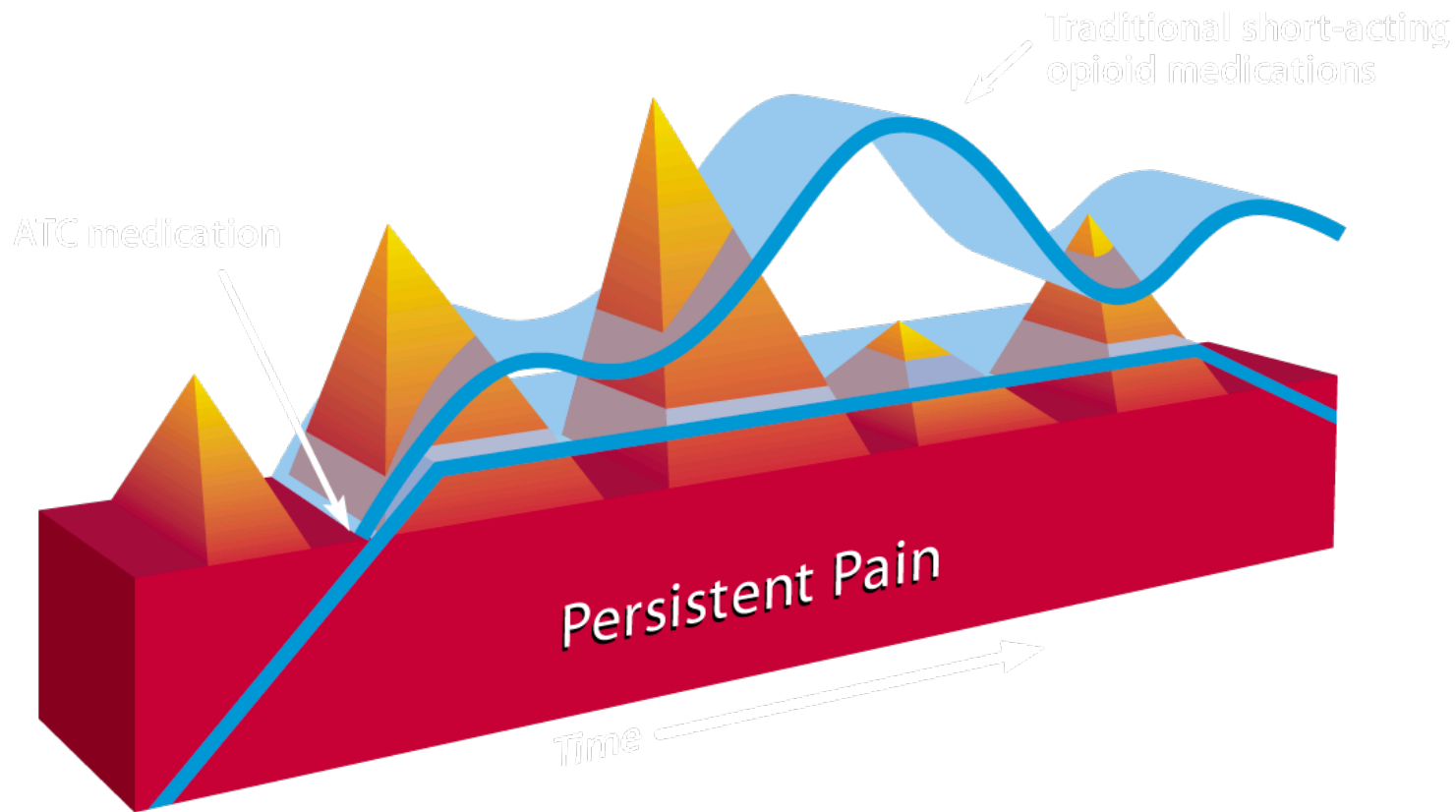




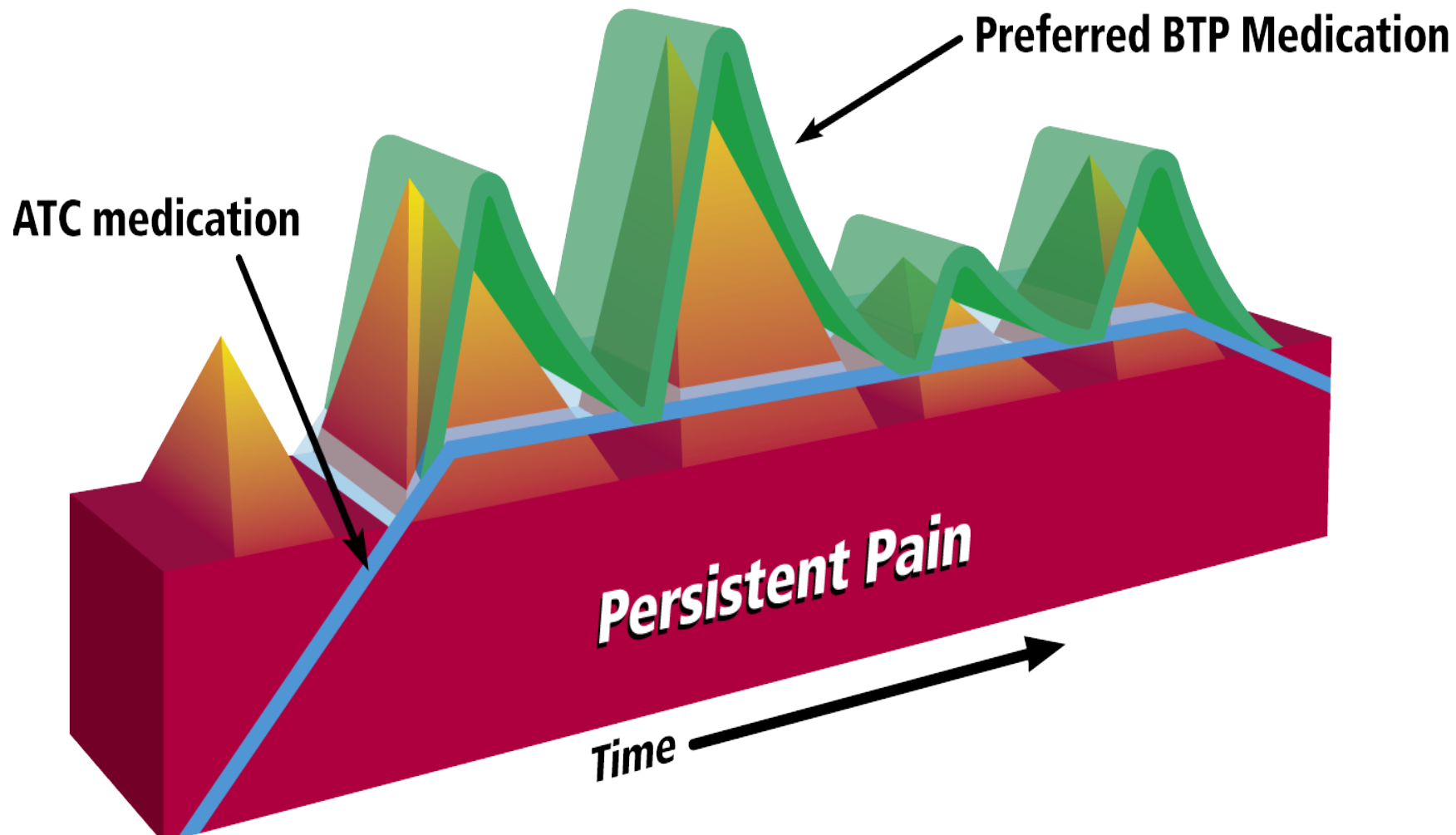
# Overtreatment of BTP With ATC Medication



# Inadequate Treatment with Traditional SAO



# Ideal BTP Treatment



# Tactical Plan

## BTP Campaign Evolution

**FENTORA<sup>TM</sup>**  
*fentanyl buccal tablet* ®

Case: 1:17-md-02804-DAP Doc #: 2557-18 Filed: 08/30/19 141 of 150. PageID #: 411948

# Expanded BTP Disease Awareness Campaign

**Goal: To continue to establish BTP as a distinct clinical problem & to facilitate dialogue between physicians and patients to improve the proper diagnosis and treatment of BTP**


➤ **Phase I (completed)**

- Understand how others in the industry have built disease states (Bipolar, HPV, Depression Pain, RLS)
- Understand physician and patient interactions around BTP
- Create a 'portrait' of our target audience
- Understand how to leverage the internet

➤ **Phase II (Nov 06 – Jan 07)**

- Create BTP messaging & concepts based on Ph I learnings
- Start enhancing BTP.com / Start to maximize internet search

➤ **Phase III (April 2007) – Execution**



Just when you think their pain is under control...

**Breakthrough pain (BTP):**  
a distinct clinical problem in patients with persistent pain, requiring diagnosis and targeted treatment

...a transitory exacerbation, or flare, of moderate-to-severe pain that occurs in patients with otherwise stable persistent pain.

BTP often goes undiagnosed and untreated, despite its devastating impact.

**For patients with BTP, hope begins with recognition – [www.breakthroughpain.com](http://www.breakthroughpain.com)**

©2006 Cephalon, Inc. All rights reserved. EDU238 Jan 2006 Printed in USA.



**FENTORA™**  
fentanyl buccal tablet @

# ***FENTORA***<sup>TM</sup> **NSM Workshops**

***FENTORA***<sup>TM</sup>  
*fentanyl buccal tablet* ®

# **FENTORA™ NSM Training Objectives:**

The purpose of the *FENTORA* training workshops are to increase the knowledge base of the PCS and OAS representatives in preparation to meet the strategic objective of; maintaining current prescribing activity with the “ACTIQ® loyalists” and expanding their prescribing universe to those physicians that treat breakthrough pain with SAO but have had limited experience with ACTIQ. This strategy will be met by implementing the following tactics in each of the proposed workshops:

- Consistently communicate *FENTORA* marketing messages
- Effectively use resources (CVA, Clinical Reprints, Formulary Kit)
- Increase reimbursement/MCO knowledge to minimize reimbursement obstacles
- Strengthen clinical proficiency
- Reinforce territory acumen through scenario driven learning (skill enhancement with HCP, critical office staff and Pharmacist)

Case 1:17-md-02804-DAP Doc #: 2557-18 Filed: 08/30/19 144 of 150. PageID #: 411951

# Workshop #1

## ***Breakthrough Barriers: Reimbursement***

### **This workshop is designed to be a 2 step process:**

- Step #1- will provide a lecturer to educate the audience on the managed care environment and provide time for Q&A
- Step #2- will provide application based learning utilizing knowledge gleaned from step #1, practice with the FENTORA Formulary Kit and sharing of best practices, successes and ideas
- **Logistics:**
  - ✔ 4 rooms w/ 4 presenters (AD's and M.Felker) for presentation (step #1)
  - ✔ 4 rooms- AM facilitators at district tables for application (step #2)

***Recommended Time:2 hours***



# Workshop #2 (Rotating w/ Workshop #3 Clinical) *Breakthrough Vision: Core Visual Aid*

Case: 1:17-md-02804-DAP Doc #: 2557-18 Filed: 08/30/19 PageID #: 411952

This workshop is designed to be a 2 step process:

- Step #1- Gallery Walk of CVA spreads
- Step #2- Application

## ➤ Logistics

- 1 room for 'Gallery walk' 75-80 participants- 12-13 attendees / spread (*rotating w/ Clinical Workshop #3*)
  - ✔ Request Marketing Participation (1 hour)
- 1 room for application/ verbalization – 1 district /table (7-10 tables)
  - ✔ AM to be district facilitators at table( 30 minutes)

***Recommended time 3 hours (due to rotation w/ CVA Workshop #3)***

# Workshop #3 (rotating w/ Workshop #2 CVA) Breakthrough Science: Clinical Proficiency

## ➤ Clinical Presentation

- ✓ 3039 data from completed trial
- ✓ 3042 and 3041 queries
  - ✓ Utilization of data in the field (potential as WLF- April time frame)

## ➤ Application Exercise

- ✓ Verbalization (99-14,1028)
  - ✓ Utilization of approved reprints

## ➤ Logistics

### ➤ Clinical Presentation (J. Messina or A. Narayana)

- ✓ 1 room w/ 75-80 attendees
- ✓ Presentation for 1 hour

### ➤ Application

- ✓ AM to be facilitator at district table
- ✓ 1 room 7-10 tables 1 district per table

**Recommended Time 3 hours** (due to rotation w/ CVA Workshop #2)

## Breakthrough Skills: Skill Refinement

### Situational Driven Aptitude

- Increasing your territory acumen based on:
  - ✦ Data Review
    - ✓ Proper customer
    - ✓ Knowledge of customer
    - ✓ Establish outcome
  - ✦ Message
    - ✓ Identify the KIC
    - ✓ Be relevant
  - ✦ Tools
    - ✓ Determine resource
    - ✓ Review resource
    - ✓ Maintain a deliberate and specific focus
  - ✦ Communication: *Dialogue Initiated- Monologue Concluded*
    - ✓ End every customer interaction with a KIS
    - ✓ **“Give your customer a “KIC” and always leave them with a “KIS”**
  - ✦ Analysis
    - ✓ Achievement of established outcome
    - ✓ Assessment of next steps

***Recommended Time 2.5 hours***

# Workshop #4:

## Breakthrough Skills: Skill Refinement (cont.)

### ➤ Logistics

- 4 rooms (optimal)
- Facilitator presents background and direction of workshop
- AM are table facilitators
- PCS/OAS develop territory specific scenarios (reality based)
  1. Representative defines outcome of call but keeps the goal concealed until after individual presentation
  2. Representative flip charts highlights of office for table
  3. Representative presents (role plays) to table utilizing peers as doctor, nurse and pharmacist
  4. Table debrief w/ peers and AM

# Additional Workshops

- Regulatory(60 minutes)
  - ✓ Compliance (mandatory)
  - ✓ Presentations broken out by sales force

Thank you!

Questions?

***FENTORA***<sup>TM</sup>  
*fentanyl buccal tablet* ®